

SCHEDULING STATUS: S0

PROPRIETARY NAME AND DOSAGE FORM:

SKABI-RID (Scabicial Lotion)

COMPOSITION:

Each 1g of lotion contains:

Permethrin 50mg

Nipastat (preservative) 0.26% m/m

PHARMACOLOGICAL CLASSIFICATION:

A 13.12 Dermatological Preparations – Other

PHARMACOLOGICAL ACTION:

Permethrin is a pyrethroid pesticide.

It acts on the nerve cell membrane of the pest to disrupt the sodium channel current by which the polarization of the membrane is regulated. This results in delayed polarization and subsequent paralysis of the pest.

INDICATIONS:

SKABI-RID is indicated for the treatment of infestations with *Sarcoptes scabiei* (scabies)

CONTRA INDICATIONS:

Not to be used by persons sensitive to permethrin or any of the ingredients.

WARNINGS:

Discontinue if hypersensitivity to SKABI-RID occurs.

Avoid contact with eyes.

For external use only.

INTERACTIONS:

None known

PREGNANCY AND LACTATION:

The safety of this preparation in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Apply lotion over whole body from ears all the way down to the soles of the feet. Leave on overnight and wash off the following morning (after eight to twelve hours). Repeat after two weeks if necessary.

Do not apply directly to the face.

SHAKE THE BOTTLE BEFORE USE.

For external use only.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

The following side effects have been reported:

Skin and subcutaneous tissue disorders:

Burning of the skin - less frequent.

Itching, stinging, redness - rare.

Precautions:

If irritation of the skin persists, consult your physician.

SKABI-Rid may be very mildly irritating to the eyes. Avoid contact with the eyes during application and flush with water immediately if the product gets into the eyes.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

If accidentally ingested employ gastric lavage. Treatment is symptomatic and supportive. (The oral LD50 for technical permethrin in rats is 430 to 4000 milligrams per kilogram (mg/kg)).

IDENTIFICATION:

A white non greasy lotion

PRESENTATION:

White pre-printed HDPE bottle with flip disc screw cap, filled with 100ml lotion. The bottle is placed in a printed outer carton.

STORAGE INSTRUCTION:

Store below 25,°C in a cool place.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER:

A40/13.2/0756

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

TomarMed (Pty) Ltd

26 Wilson St

Knysna

6570

South Africa

MARKETED BY:

Glenmark Pharmaceuticals SA (Pty) Ltd

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Tybalt Place

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DATE OF PUBLICATION OF INSERT:

05 March 2009

PATIENT INFORMATION LEAFLET

Read this entire leaflet carefully because it contains important information for you.

This medicine is available without a doctor's prescription for you to treat a mild illness. Nevertheless you still need to use SKABI-RID carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

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SKABI-RID Scabicial lotion.

Permethrin 5%

1. WHAT SKABI-RID CONTAINS

- The active substance is permethrin 50mg per 1 g lotion.
- The other ingredients are Nipastat (preservative) Carbopol Ultrez 10, Crodamol Cap, Disodium edetate, Polysorbate 80, Sorbitan oleate, Propylene glycol, Trometamol and purified water.

2. WHAT SKABI-RID IS USED FOR

SKABI-RID is used for the treatment of scabies.

3. BEFORE YOU USE SKABI-RID

Do not use SKABI-RID if you are sensitive to permethrin or any of the other ingredients.

Pregnancy and breast feeding:

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Using other medicines with SKABI-RID:

If you are taking other medicines on a regular basis including complementary or traditional medicines, the use of SKABI-RID with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO USE SKABI-RID

Apply lotion over whole body from ears all the way down to the soles of the feet. Leave on overnight and wash off the following morning (after 8 to 12 hours). Repeat after two weeks if necessary.

Do not apply directly to face

SHAKE BOTTLE BEFORE USE

For external use only

If you have the impression that the effect of SKABI-RID is too strong or too weak, talk to your doctor or pharmacist.

If you use more SKABI-RID than you should:

In the event of over dosage, consult your doctor or pharmacist. If neither is available seek help at the nearest hospital or poison centre.

5. POSSIBLE SIDE EFFECTS

SKABI-RID can have side effects.

Burning of the skin can be experienced after application of the lotion.

Mild itching, stinging and redness can also be experienced.

Not all side effects for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF SKABI-RID

Store below 25°C, in a cool place.

Keep all medicines out of reach and sight of children.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

7. PRESENTATION OF SKABI-RID

White pre-printed bottle with flip disc screw cap, filled with 100ml lotion. The bottle is placed in a printed outer carton.

8. IDENTIFICATION OF SKABI-RID

A white non greasy lotion.

9. REGISTRATION NUMBER

A 40/13.2/0756

10. NAME AND ADDRESS OF REGISTRATION HOLDER

TomarMed (Pty) Ltd

26 Wilson St

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11. DATE OF PUBLICATION

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