PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

SKABI-RID LOTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of lotion contains:

Permethrin	50 mg
Nipastat (preservative)	0,26 % m/m

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lotion.

A white non-greasy lotion.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

Posology

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.

Paediatric population

The safety and efficacy of SKABI-RID LOTION in children have not yet been established (see section 5.1).

Method of administration

To be applied topically.

4.3 Contraindications

Hypersensitivity to permethrin or to any of the excipients.

4.4 Special warnings and precautions for use

- SKABI-RID LOTION 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.
- If irritation of the skin persists, consult your physician (see section 4.8).

SKABI-RID LOTION contains polysorbate 80. Polysorbates can cause allergic reactions.

Paediatric population

The safety and efficacy of SKABI-RID LOTION in children have not yet been established (see section 5.1).

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

The safety of SKABI-RID LOTION in pregnancy and lactation has not been established.

Fertility: No data available.

4.7 Effects on ability to drive and use machinery

Permethrin has no or negligible influence on the ability to drive and use of machines (see section 4.8).

4.8 Undesirable effects

The most reported side effect is burning of the skin.

System Organ Class	Frequency	Undesirable effect
Skin and subcutaneous tissue disorders	Less frequent	Burning of the skin
	Rare	Itching, stinging, redness

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the

Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

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)).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 13.12 Dermatological Preparations – Other

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.

Paediatric population

No information available on the use of SKABI-RID LOTION.

5.2 Pharmacokinetic properties

No pharmacokinetic studies have been performed on SKABI-RID LOTION.

5.3 Preclinical safety data

No preclinical safety data available on SKABI-RID LOTION.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Carbopol Ultrez 10
- Crodamol Cap
- Nipastat
- Disodium edetate
- Polysorbate 80 (Tween 80)
- Sorbitan oleate (Crill 4)
- Propylene glycol
- Trometamol (Tromethamine)
- Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months if stored below 25 °C in a cool place.

6.4 Special precautions for storage

This medicine does not require any special storage conditions.

6.5 Nature and contents of container

White pre-printed HDPE bottle with flip disc screw cap, filled with 100 ml lotion.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER

A40/13.2/0756

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05 March 2009

10. DATE OF REVISION OF TEXT

20-October-2026