Patient leaflet in accordance with the Pharmacists' Regulations (Preparations)- 1986
This medicine is dispensed without a doctor's prescription

Prilidan
Cream

The active ingredients and their concentration:
2.5% lidocaine
2.5% prilocaine

Inactive ingredients and allergens in the medicine - see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.
Use the medicine according to the instructions in the dosage section in this leaflet. Consult a pharmacist if you need additional information.

1. What is the medicine intended for?
Topical anesthetic used to relieve skin pain before procedures such as needle pricks and superficial skin operations.

Therapeutic group: Local anesthetic of the amide group.

Prilidan works by temporarily numbing the skin surface so that it helps relieve the pain. However, you may still feel touch and pressure in the area.

2. Before using the medicine

Do not use the medicine:
If you are sensitive (allergic) to the active ingredients or to any of the other ingredients the medicine contains or to another similar local anesthetic (see section 6).

Special warnings regarding the use of the medicine:

Before treatment with Prilidan cream, tell the doctor if:
- You or your child have a rare inherited illness that affects the blood, called "glucose-6-phosphate dehydrogenase (G6PD enzyme) deficiency" (sensitivity to fava beans).
- You or your child have a problem with blood pigment levels called "methemoglobinemia".
- Do not use Prilidan cream on areas with skin rash, cuts, grazes, scratches or other open wounds, with the exception of a leg ulcer. If any of these problems is present, check with the doctor or pharmacist before using the medicine.
- You or your child have itchy skin condition called "atopic dermatitis". A shorter application time on the skin may be sufficient.
  Application times of the cream on the skin for more than 30 minutes can cause an increase in the incidence of local skin reactions (see also section 4 "Side effects").
- You take particular medicines for heart rhythm disorders (class III antiarrhythmics, such as amiodarone). In that case the doctor will monitor your heart function.

Due to the potentially enhanced absorption on newly shaven skin, it is important to follow the recommended dosage, skin area and application time of the cream on the skin.
Avoid contact with the eyes, as it may cause irritation. If Prilidan cream accidentally gets in the eyes, immediately rinse the eyes well with lukewarm water or a salt (sodium chloride) solution. Be careful to avoid getting anything in the eye until feeling returns.
Do not apply Prilidan cream to an impaired eardrum.

When you use Prilidan cream before being vaccinated with live vaccines (e.g., tuberculosis vaccine), you should return to the doctor or nurse after the time period requested to follow-up the vaccination result.
In children – do not use on the genital mucosa (see also in section 3).

In the following cases consult the doctor before starting the treatment:

- In infants under one year of age that are being concomitantly treated with methemoglobinemia inducing medicines such as sulfonamides ("sulfa drugs").
- In premature infants until they have reached the chronological age of 37 weeks of pregnancy.

Drug interactions

If you are taking, or have recently taken other medicines, including nonprescription drugs, nutrition supplements and herbal remedies, tell the doctor or pharmacist. This is because Prilidan cream can affect the way certain medicines work, and some medicines can have an effect on the activity of Prilidan cream.
In particular, tell the doctor or pharmacist if you are taking:

- Medicines used to treat infections, called sulfonamides, and nitrofurantoin.
- Medicines used for the treatment of epilepsy, called phenytoin and phenobarbital.
- Other local anesthetics.
- Medicines for the treatment of uneven heartbeat, such as amiodarone.
- Cimetidine or beta-blockers, which may cause an increase in the blood levels of lidocaine. This interaction is of no clinical relevance in short-term treatment with Prilidan cream at the recommended dosages.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult the doctor or pharmacist before using this medicine.
Occasional use of Prilidan during pregnancy is unlikely to cause any adverse effects on the fetus.
The active ingredients in Prilidan cream (lidocaine and prilocaine) are passed into breast milk. However, the amount is very small so there is generally no risk to the child.
Animal studies have shown no impairment of male or female fertility.

Driving and using machines
Prilidan cream has no or negligible influence on the ability to drive and use machines when used at the recommended doses.

Important information about some of the ingredients of this medicine
Prilidan contains polyoxyl 40 hydrogenated castor oil. This substance may cause skin reactions.

3. How to use the medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
See further down: "Measuring the correct amount of cream".
Do not use Prilidan cream on mucous membranes or on damaged skin without consulting the doctor. In such cases reduce the application time of the cream.

Recommended dosage unless otherwise instructed by the doctor:

<u>Dosage in adults (over 12 years of age):</u>
For minor surgical procedures (such as needle insertion for an I.V. infusion or when taking blood tests, or curettage of viral skin lesions (mollusca contagiosum):
Approximately 1.5-2 grams for each 10 cm^2 area of skin. Apply a thick layer of the cream, cover it with an occlusive dressing, such as plastic wrap, and wait 1-5 hours.
For surgical procedures requiring deeper local anesthesia:
Approximately 1.5-2 grams for each 10 cm^2 area of skin. Apply a thick layer of the cream, cover it with an occlusive dressing, such as plastic wrap, and wait 2-5 hours.
Maximum dosage: Up to 60 grams per 24 hours (2 tubes of 30 grams) may be applied. Do not leave the cream on the treated area for longer than 5 hours.
For recently shaven skin areas, do not apply Prilidan cream to an area larger than 600 cm^2 (20 x 30 cm).
For removal of leg ulcers – apply 1-2 grams for each 10 cm^2 area of skin. Apply a thick layer of cream on

the area of the ulcer, but not more than 10 grams for each treatment. Cover with an occlusive dressing and dispose of any remaining cream left in the tube. Application time: at least 30 minutes. In cases of tissues with particularly difficult permeability, the application time can be extended to a maximum of 60 minutes. Ulcer removal should begin within 10 minutes after cream removal. Prilidan can be used for up to 15 treatments over a period of 1-2 months without a decrease in the effect or an increase in the number of local reactions.

On genitalia (men only) – before injection of local anesthetics – apply approximately 1 gram for each 10 cm^2 area of skin. Cover with an occlusive dressing for 15 minutes.
On genitalia (women) – before injection of local anesthetics – apply approximately 1-2 grams for each 10 cm^2 area of skin. Cover with an occlusive dressing for 60 minutes.
On genital mucosa (adults only) – prior to minor skin surgeries such as surgery for removing condylomas: apply 5-10 grams, depending on the size of the treated area. Cover the whole area, including the mucosal folds. Occlusion is not necessary. Application time: 5-10 minutes.
Start the surgery immediately after removal of the cream.

Dosage in children:

For use on the skin before medical procedures such as needle insertion or minor skin surgeries. Apply about an hour before the procedure.
Do not exceed the recommended dose (see dosage table).
When used in infants up to 3 months of age, methemoglobin should be checked before and after use.
In children, do not use Prilidan on the genital mucosa.

Dosage table in infants and children:

Age/body weight	**Maximal amount of Prilidan cream**	**Maximal application area**	**Maximal application time on the skin**
Up to 3 months/up to 5 kg	1 gram	10 cm^2	1 hour
3-12 months/5-10 kg	2 grams	20 cm^2	4 hours
1-6 years/10-20 kg	10 grams	100 cm^2	4 hours
7-12 years/over 20 kg	20 grams	200 cm^2	4 hours

In children with atopic dermatitis, remove the cream 15-30 minutes after application.

Applying additional doses:
In infants up to 3 months of age – do not apply another dose for 24 hours.
In infants and children over 3 months of age – wait at least 12 hours until reapplying Prilidan. Do not apply more than 2 doses within 24 hours.

Measuring the correct amount of cream (for use in children and adults):

A strip of cream that is about 3.5 cm long is approximately equal to 1 gram of cream.

Do not exceed the recommended dose.

See detailed instructions for use at the end of this leaflet.
Do not swallow! This medicine is intended for external use only.
Avoid contact of the medicine with the eyes, mucous membranes and ears. In case of contact, wash thoroughly with water. Protect the eye until sensation is restored to the eye.

If you have applied more than recommended, you may experience: bluish-gray colored skin, drowsiness or dizziness, blurred vision or ringing in the ears, changes in the sense of taste, confusion, hot/cold or paresthesia sensation, tingling of the skin around the mouth and numbness of the tongue. In severe cases of overdose there may be fits, decrease in blood pressure, slowed breathing, stopped breathing and altered heart rate – evacuate the patient to the emergency room immediately!

If you have applied more Prilidan cream than recommended or if a child or someone else has accidentally swallowed the medicine, proceed immediately to a doctor or hospital emergency room and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of Prilidan cream may cause side effects in some users. Do not be alarmed while reading the list of side effects; you may not suffer from any of them.

Refer to your doctor or pharmacist if any of the following side effects bother you or does not seem to be passing. Tell the doctor about anything else that is causing you to feel unwell while you are using Prilidan cream.

If you experience any of the following effects while you are using Prilidan cream, stop using it and check with your doctor or pharmacist as soon as possible:

- Allergic reactions, which in rare cases may develop into anaphylactic shock (skin rash, swelling, fever, respiratory difficulties and fainting) during treatment of skin, genital mucosa or leg ulcers.
- Methemoglobinemia (blood disorder), which in rare cases may develop during treatment of the skin, and may cause signs and symptoms of hypoxemia (abnormally low levels of oxygen in the blood), which can lead to a change in the color of the skin to bluish-gray. Methemoglobinemia is more frequently observed, often in connection with overdose, in newborn infants and infants aged 0 to 12 months.

A mild reaction (paleness or redness of the skin, slight puffiness, an initial burning sensation or itching) may occur on the area on which Prilidan cream is applied. These are normal reactions to the cream and the anesthetic ingredients, and they will disappear within a short time without any additional measures being needed.

If you experience worrisome or unusual effects when you use Prilidan cream, stop using the cream and check with your doctor or the pharmacist as soon as possible.

Common side effects (appear in 1-10 users out of 100):

- Transient local skin reactions (paleness, redness, swelling) in the treated area during treatment of skin, genital mucosa or leg ulcers.
- An initially mild sensation of burning, itching or warmth in the treated area during treatment of genital mucosa or leg ulcers.

Uncommon side effects (appear in 1-10 users out of 1,000):

- An initially mild sensation of burning, itching or warmth in the treated area during treatment of the skin.
- Numbness or sense of tingling in the treated area during treatment of genital mucosa.
- Irritation of the treated skin during treatment of leg ulcers.

Rare side effects (appear in 1-10 users out of 10,000):

- Small dot-shaped bleeding on the treated area (particularly on children with eczema after longer application times of the cream) during treatment of the skin.
- Irritation of the eyes if Prilidan cream accidentally comes into contact with them during treatment of the skin.

If a side effect appears, if one of the side effects worsens, or when you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects and drug interactions in children and infants:
Parents must inform the attending doctor about any side effects, as well as any additional medicine being given to the child. See above detailed side effects and particular drug interactions.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store the medicine below 25˚C. Do not freeze.
- Prilidan cream can be used up to 6 months after first opening the tube, but not later than the expiry date.
- The medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:
polyoxyl 40 hydrogenated castor oil, carbomer, sodium hydroxide, purified water.

What the medicine looks like and contents of the package:
A white soft cream packaged in a package containing a single 30 g aluminum tube of cream.

Registration holder and address:

Halperin NH Medic Ltd., 19 Zur St., Ma'ayan Zvi 30805.

Manufacturer and address:

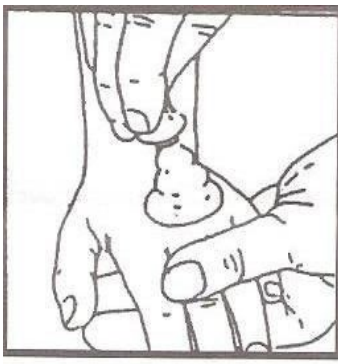
Rafarm S.A. 12 Korinthou St., 154 51 N Psihiko, Athens, Greece.

Revised in February 2022 according to MOH guidelines.

Drug registration number at the national medicines registry of the Ministry of Health: 157-87-34381

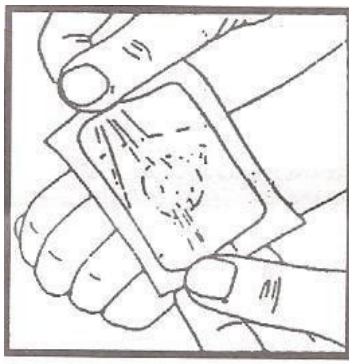
<u>Directions for use</u>:

1. Squeeze the Prilidan tube to extract a sufficient amount (see dosage instructions) and apply a thick layer of the cream on the skin. Do not rub the area.



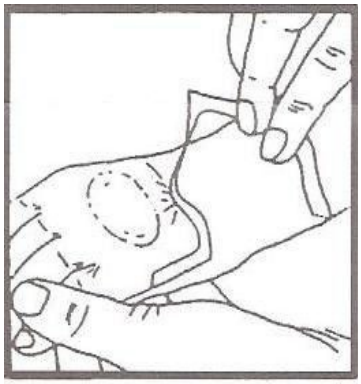
1

2. Cover the skin to which Prilidan was applied with an occlusive dressing, such as plastic wrap. Secure it firmly, make sure that all of the cream is covered.



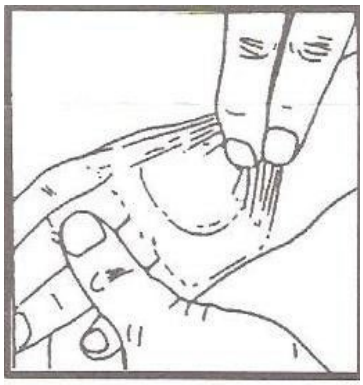
2

3. Wait the necessary period of time (usually at least an hour) before performing the required treatment.



3

4. Remove the dressing, wipe off Prilidan cream and prepare for the required treatment. The area treated with Prilidan will remain anesthetized for at least 30 minutes and up to several hours.



4