

PATIENT INFORMATION LEAFLET

Lokaril Cream 5 %

Apply on the skin

- **Active substance** : Each 1 gram contains 25 mg lidocaine (%2.5) and 25 mg prilocaine (%2.5)
- **Excipients** : Croduret 54 (PEG-54 hydrogenated castor oil), Synthalen MP (Carbomer), Sodium hydroxide pellet, deionised water

Read all of this leaflet carefully before you start using this medicine because it contains important information for you

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others.

Tell your doctor if you go to a doctor or a hospital when you are using this medicine.

*Follow these instructions exactly. Do not use **high or low** doses other than the recommended dose for the drug.*

What is in this leaflet

1. ***What LOKARİL is and what it is used for***
2. ***What you need to know before you use LOKARİL***
3. ***How to use LOKARİL***
4. ***Possible side effects***
5. ***How to store LOKARİL***

1. **What LOKARİL is and what it is used for ?**

Lokaril cream is a local anesthetic applied on the skin (narcotics). It provides loss of sensation with temporary numbness in the area where it is applied. Nevertheless, there is a feeling that you touch the applied region. Lokaril cream is applied on skin, genital (reproductive organs) mucosa and leg ulcers.

Lokaril cream is available in 5 g and 10 g aluminum tubes

- Lokaril cream is used in needle application and small skin surgery to reduce the pain on the skin before intervention.
- Lokaril cream can also be applied on the genital mucosa prior to surgery or other local anesthetics injected.

- Lokaril cream is also used to relieve pain in leg ulcers to facilitate cleansing.

2. What you need to know before you use LOKARİL

Do not use LOKARİL

- If you have hypersensitivity to lidocaine, prilocaine or any compound present in the formulation of Lokaril
- Do not use Lokaril cream in premature newborn babies.
- Do not use in babies 12 months of age who are treated with the same medications as other medications that affect the levels of methemoglobin in the blood.

Warnings and precautions

- If you experience any unusual or unpleasant allergic condition when using Lokaril cream or any other medication, be sure to inform your doctor.
- Do not use lokaril cream except leg ulcers, other open wounds, cuts and exanthematous skin.
- Do not contact Lokaril cream with eyes. May cause irritation. If it accidentally come into contact with your eyes, wash your eyes immediately with lukewarm water or sodium chloride solution and protect your eyesight until a loss of sight.
- Lokaril cream is not applied to ear hair damage.
- If you use Lokaril cream before the vaccine applicated to skin (eg tuberculosis vaccine), consult with your doctor after the vaccination result is followed.
- Tell your doctor if you have a rare metabolic problem, such as glucose-6-phosphate dehydrogenase deficiency or congenital or unexplained methemoglobinemia. (Methemoglobin is a condition in which the excess of hemoglobin is converted to methemoglobin. Normally, hemoglobin is present in a small amount in a form called methemoglobin in the blood, and if too much methemoglobin is formed, the blood becomes difficult to carry oxygen into the body)
- If you or your child have atopic dermatitis, be sure to apply the cream for up to 30 minutes.

If you have ever had any of these conditions, tell your doctor before you use KOLISTATE

LOKARİL with food and drink

There is no interaction with food and drink due to the way of use (skin or mucosa)

Pregnancy

Consult your doctor or pharmacist before using the medicine

If you are pregnant, think you may be pregnant or planning to have a baby, inform your doctor before taking this medicine.

Consult your doctor or pharmacist if you notice that you are pregnant during treatment.

Lactation

Consult your doctor or pharmacist before using the medicine

Lokaril cream may pass through a very small amount of human breast milk but does not pose a risk to the baby.

Effects on ability to drive and use machines

Lokaril cream does not affect the ability to drive and use machines.

Important information about some of the excipients present in LOKARİL

If you do not have an extreme sensitivity to excipients in the lokaril cream content, there is no adverse effect due to these substances.

LOKARİL with other medicinal products

Please tell your doctor if you are taking or have recently taken any other medicines, given below.

- Drugs known to stimulate methemoglobinemia (e.g., sulfonamides),
- Other local anesthetics (narcotics) or drugs similar to the local anesthetic structure (eg tocaïnide)
- Class III antiarrhythmic drugs (cardiac rhythm regulating drugs, eg amiodarone)
- Drugs that reduce the excretion of lidocaine from the kidneys (eg cymetidine or betablokers)

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3.How to use LOKARİL ?

Instructions for proper use and dose / application frequency:

Information about the general dose of the Lokaril cream will be provided in this section. Your doctor will determine the required dose quantity. If you want to take full advantage of this drug, you have to follow the information in this section.

You can deflect the protective membrane of the tube using the sharp tip in the head

- Application of Lokaril cream on skin

Apply a thin layer on the skin. Cover with an airtight material such as Tegaderm or plastic wrap. For approximately 2 g of Lokaril cream, use a 5 g tube half.

Surgical interventions in small areas, eg needle penetration and surgical treatment of local lesions: apply approximately 2 g for at least 1 hour up to 5 hours.

Interventions in large areas, such as placing a piece taken from intact skin to skin loss site or skin biopsy where a deeper anesthesia is required, interventions in large areas, it is applied at a rate of about 1.5-2 g for a period of at least 2 hours, a maximum of 5 hours at 10 cm² area.

New shaved skin surfaces in large body areas (maximum recommended treatment area is 600 cm² - this corresponds to a paper size of approximately A4 size of 30 * 20 cm): it is applied at least 1 hour to max 5 hour, at least 1 g / 10 cm² region. The maximum recommended dose is 60 g.

- Application of Lokaril cream to certain skin problems

If you have skin problems such as atopic dermatitis or molluscum (obvious disease with small nodules on the skin), a shorter application period of 15-30 minutes may suffice.

- Application of Lokaril cream to the genital mucosa membrane or genitalia

Genital mucosa membrane: Surgical treatment of local lesions such as removal of genital warts: Lokaril cream is applied by your doctor or nurse 5-10 minutes before surgical intervention. Normal dose is 5-10 g Lokaril cream for 5-10 min. The applied region must be covered over. It should be attempted immediately afterwards.

Male genitalia: It is used as directed by your physician prior to application of local anesthesia. The normal dose is 1 gram on a 10 cm² area for 15 minutes.

Female genitalia: It is used as directed by your physician prior to application of local anesthesia. The normal dose is 1-2 grams over a 10 cm² area for 60 minutes.

- Use of Lokaril cream in leg ulcers

The cream is covered tightly with a plastic wrapper so that it does not overflow after it is applied in the leg ulcers. The application period is at least 30 minutes. A 60-minute application can provide more anesthesia. Wipe the cream with a gauze. Washing should be started immediately after cleansing the cream.

Approximately 1-2 g, up to 10 g of Lokaril cream is applied as a thick layer on a 10 cm² area in leg ulcers. Lokaril cream can be applied before washing your leg ulcers more than 15 times in 1-2 months.

Use of administration and method:

It is applied on skin, genital mucosa or genital skin and leg ulcers.

Different age groups

Pediatric population :

- Application of Lokaril cream on skin

Surgical interventions in small areas, eg needle penetration and surgical treatment of local lesions: apply approximately for 1 hour.

Newborns and infants 3 months old:

Apply a maximum 1 gram cream to a region of max. 10 cm². Application period should not exceed 1 hour.

3-11 month old infants:

Apply maximum 2 grams cream to a region of max. 20 cm². The duration of application is approximately 1 hour (maximum 4 hours).

Children between 1-5 years:

Apply maximum 10 grams cream to a region of max. 100 cm². The duration of application is about 1 hour (max 5 hours).

Children between 6-11 years :

Apply maximum 20 grams cream to a region of max. 200 cm². The duration of application is about 1 hour (max 5 hours).

-Lokaril cream applied in some skin problems

For children with atopic dermatitis, 30 minutes of Lokaril cream is recommended for removal of molluscan.

- Application of lokaril cream to genital mucosa membrane or genital skin

Lokaril cream should not be applied to genital mucosa membranes in children.

If you think that the effect of LOKARİL is very strong or weak talk to your doctor or pharmacist.

If you use more LOKARIL than you should :

Symptoms that may occur when you use the highest amount are: numbness on the lips and mouth, dizziness, drowsiness, and sometimes blurred vision. If you have used too much Lokaril cream even if there is no symptom, you should contact your doctor immediately or the emergency department of a health institution. No toxic effects were observed at doses recommended by doctor.

When too much Lokaril cream is used in combination with certain medicines, acute methemoglobinemia rash appears. Methemoglobinemia can be understood with the sign of cyanosis (deep gray-blue coloring). Such a condition can be treated by intravenous injection of methylene blue.

If you use Lokaril cream more than you need to use, talk to a doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects if you have hypersensitivity to any compound present in the formulation

If the following side effects arise as a result of the use of Lokaril cream, and if it continues consult your doctor. These reactions are usually short-lived and their effects diminish over time.

Side effects are listed as follows:

Very Common ($\geq 1/10$)

Common ($\geq 1/100$ to $< 1/10$),

Uncommon ($\geq 1/1,000$ to $< 1/100$),

Rare ($\geq 1/10,000$ to $< 1/1,000$),

Very rare ($< 1/10,000$),

Not known (can not be predicted from available data)

If the following symptoms will be seen in your case and if it continues, tell your doctor.

Common side effects:

- Paleness, redness and swelling in the area affected (edema)
- Slight burning at the moment of first application, itching

These are slight side effects of Lokaril cream and disappear in a short time.

Rare side effects:

- Allergic reactions in local anesthetics (the most severe of these reactions is anaphylactic shock). It can be seen with the use of Lokaril rarely.

- Methemoglobinemia (deep blue-gray colouring)
- Children with skin problems (atopic dermatitis or molluscus) may have small red dots in the application area.
- It may be irritating to the eye if the Lokaril cream accidentally comes into contact with the eye.

These are rare side effects of Lokaril cream. If you notice any of these effects, stop using Lokaril cream and report it to your doctor immediately.

If you experience any side effects not mentioned in this patient information leaflet, inform your doctor or pharmacist.

Reporting of suspected adverse reactions

Talk to your doctor, pharmacist or nurse if you have any side effects located or not in patient information leaflet. In addition, notify the side effects you are experiencing to www.titck.gov.tr site by clicking "Drug side effects notification" icon or by calling 0 800 314 00 08 numbered side effect statement line Turkey Pharmacovigilance Center (TÜFAM). By reporting side effects, you will contribute to learning more about the safety of the medicine you are using.

5. How to store LOKARİL ?

Keep LOKARİL out of the sight and reach of children, in its package.

Store at room temperature below 25°C in original package. Do'nt freeze.

Use in accordance with expiration date

Do not use LOKARİL after the expiry date which is stated on the carton

Do not use LOKARİL if you notice that the pack is damaged or show signs of tampering.

Marketing Authorisation Holder : Biem İlaç San. ve Tic. A.Ş.
Anıttepe Mah. Turgut Reis Cad. No: 21
Tandoğan / Çankaya – Ankara

Manufacturer : Vefa İlaç San. ve Tic. Ltd. Şti
Beylikdüzü/ İstanbul /Turkey

This leaflet was approved in