

JETEX® 5% cream

Applied on the skin.

• **Drug substance:** 1 gram of cream contains 25 mg of lidocaine and 25 mg of prilocaine.

• **Auxiliary substances:** Polyoxyethylene fatty acid ester, polyacrylic acid, sodium hydroxide, purified water

Before you start using this medication, read this DIRECTIONS FOR USE carefully, as it contains important information for you.

- Keep this directions for use. You may need to read it again later.
- If you have any additional questions, please consult your doctor or pharmacist.
- This medication is personally prescribed for you, do not give it to others.
- When you go to the doctor or hospital during the use of this medication, tell your doctor that you are using this medication.
- Follow exactly what is written in this direction. Do not use high or low doses other than the dose recommended to you for the medication.

In this Directions for Use the following titles are included:

- 1. What is JETEX® cream and what is it used for?**
- 2. Things to consider before using JETEX® cream**
- 3. How to use JETEX® cream?**
- 4. What are the possible side effects?**
- 5. Storage of JETEX® cream**

1. What is JETEX® cream and what is it used for?

JETEX® cream is a local anesthetic which is applied on skin. It provides sensory loss with temporary numbness in the area where it is applied. However, there is a feeling when you tap the applied area. JETEX® cream is applied on the skin, genitals (reproductive organs), mucosa and leg ulcers.

JETEX® cream is available in 1 packet of 5 g or 15 g tube.

- JETEX® cream is used in needle application and small skin surgery to reduce pain on the skin before intervention.
- JETEX® cream can also be applied to the genital mucosa before surgical interventions or injection of other local anesthetics.
- JETEX® cream is also used to relieve pain in leg ulcers to facilitate cleaning.

2. Things to consider before using JETEX® cream

DO NOT use JETEX® cream in the following situations.

- Do not use this medication if you are allergic to lidocaine, prilocaine or any ingredient in JETEX® cream.
- Do not use JETEX® cream on premature newborn babies.
- Do not use in infants younger than 12 months who are being treated concurrently with other medicines which affect methemoglobin levels in the blood.

USE JETEX® cream CAREFULLY in the following situations.

- If you have encountered an unusual or unpleasant allergic situation while using JETEX® cream or any other medicine, you should definitely inform your doctor.
- Do not use JETEX® cream on open wounds, cuts and rashes, except for leg ulcers.
- Do not get JETEX® cream in contact with the eyes. May cause irritation. In case of accidental contact with your eyes, immediately wash your eyes with warm water or sodium chloride solution and protect your eyes until the loss of sensation is gone.
- JETEX® cream should not be applied on the damaged eardrum.
- When you use JETEX® cream before intradermal vaccination (for example, tuberculosis vaccine), talk to your doctor after the follow-up period of vaccination result.
- If you have a rare metabolic problem such as glucose-6-phosphate dehydrogenase deficiency or congenital or unknown methemoglobinemia, inform your doctor.
- (Methemoglobin is a condition in which excess hemoglobin is converted into methemoglobin. Normally, a small amount of hemoglobin is present in the blood in a form called methemoglobin. If too much methemoglobin is formed, it becomes difficult for the blood to carry oxygen throughout the body.)
- If you or your child has atopic dermatitis (eczema), make sure that the cream is applied for a maximum of 30 minutes.
- It should only be applied on intact skin in newborns, infants and children, not on genital (reproductive organs) mucus.
- In the studies, the pain relief effect of lidocaine/prilocaine cream in the heel blood drawing procedure in newborns could not be determined.
- Single dose of the JETEX® cream is effective and safe in infants under three months of age. After applying lidocaine/prilocaine cream in infants of this age group, there was an increase in methemoglobinemia levels up to 13 hours, but these were not clinically significant.
- JETEX® cream should not be used in combination with drugs that may lead to an increase in methemoglobin levels in infants between 0-12 months until sufficient clinical experience is obtained.
- It may lead to cardiac dysrhythmia, respiratory distress, coma and even death, especially when applied to large skin surfaces and especially under occlusion (vascular occlusion).

• JETEX® cream contains polyoxyethylene fatty acid ether. This may cause skin reactions.

• Since the cardiac effects of lidocaine and class III antiarrhythmic (used against cardiac dysrhythmia) drugs (for example, amiodarone) are additive (total effect), patients using these drugs should be kept under close observation and the electrical activity of the heart should be graphically displayed via ECG (It is a device that graphically records the electrical activity of the heart (rhythm, frequency, rhythm of heartbeat, spread and disappearance of reaction) through electrodes attached to the skin).

"If these warnings apply to you, even at any time in the past, please consult your doctor."

Use of JETEX® cream with food and beverages

When applied on the skin and mucosa, the effect of JETEX® cream does not change with food and beverages.

Pregnancy

Consult your doctor or pharmacist before using the medication.

If you are pregnant or thinking of getting pregnant notify your doctor before using JETEX® cream.

If you find that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Lactation

Consult your doctor or pharmacist before using the medication.

JETEX® cream can penetrate to breast milk in a very small amount, but does not pose a risk to the baby.

Vehicle and machine use

JETEX® cream does not change the ability to drive and use machines.

Important information about some of the auxiliary substances of JETEX® cream

If you are not hypersensitive to the auxiliary substances in the content of JETEX® cream, no adverse effects are observed due to these substances. JETEX® cream contains polyoxyethylene fatty acid ether. This may cause skin reactions.

Concomitant use with other drugs

In particular, tell your doctor if you are using the following drugs:

- Drugs known to induce methemoglobinemia (e.g. sulfonamides, acetanilide, aniline dye, benzocaine, chloroquine, dapson, metoclopramide, naphthalene, nitrates and nitrites, nitrofurantoin, nitroglycerin, nitroprusside, pamaquine, para-aminosalicylic acid, phenacetin, phenobarbital, phenacetin, phenobarbital, phenytoin, primaquine, quinine),
- Other local anesthetics or medications similar in structure to local anesthetics (e.g., tetracaine),
- Class III antiarrhythmic drugs (heart rhythm regulators, e.g., amiodarone)
- Drugs that reduce the renal excretion of lidocaine (e.g., cimetidine or beta-blockers)

If you are currently using or have recently used any prescription or non-prescription drugs, please inform your doctor or pharmacist about them.

3. How to use JETEX® cream?

Instructions for appropriate use and dose/frequency of application:

This section provides information about JETEX® cream's general dose of usage. Your doctor will determine the amount of dose you need to take. If you want to take full advantage of this medication, please follow the information in this section.

You can pierce the protective membrane of the tube using the spike in the hood.

- Application of JETEX® cream on the skin:

Apply a thin layer on the skin with the help of a wooden spatula and cover with an airtight material such as plastic wrap.

Interventions in small areas of the skin, e.g., needle pricking and surgical treatment of local lesions: Apply approximately 2 g to an area of 10 cm² for minimum 1 hour and maximum 5 hours and make a closed dressing.

Interventions in large areas of the skin, where deeper anesthesia is required in the hospital setting, such as placing a piece of intact skin in the area of skin loss or skin biopsy: Approximately 1.5-2 g is applied as a thick layer on a 10 cm² area for minimum 2 hours and maximum 5 hours, and make a closed dressing.

Freshly shaved skin surfaces on large body areas (maximum recommended treatment area, 600 cm²-this area corresponds to an approximate A4 paper size of 30x20 cm): Apply for minimum 1 hour and maximum 5 hours. The maximum recommended dose is 60 g.

- Application of JETEX® cream for some skin problems

If you have skin problems such as atopic dermatitis or molluscum (significant disease with small lumps on the skin), a shorter application time of 15-30 minutes may be sufficient.

- Application of JETEX® cream to the genital mucous membrane or genital skin

Genital mucous membrane: Surgical treatment of local lesions such as removal of genital warts: JETEX® cream is applied 5-10 minutes before the surgery by your doctor or nurse. The usual dose is 5-10 g of JETEX® cream for 5-10 minutes procedures. The applied area should be covered. Closed dressing is not required. Then, immediate action should be taken. People who apply or remove the cream frequently should avoid contact to avoid sensitivity.

Male genital skin: It is used as specified by your doctor before the application of local anesthesia. The normal dose is 1 g over 10 cm2 area for 15 minutes.

Female genital skin: It is used as specified by your doctor before the application of local anesthesia. The normal dose is 1-2 g over 10 cm2 area for 60 minutes.

- Use of JETEX® cream in leg ulcers

After applying the cream for leg ulcers, cover it tightly with a plastic bandage in an air-tight way. The application time is at least 30 minutes. A 60-minute application can provide more anesthesia. Wipe out the cream with a gauze. After cleaning the cream, washing process should be started immediately.

In leg ulcers, no more than 10 g of JETEX® cream is applied in a thick layer to approximately 1-2 g of 10 cm2 area. JETEX® cream can be applied more than 15 times in a 1-2 months period before washing leg ulcers.

Route and method of administration:

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

Different age groups:

Use in children:

- Application of JETEX® cream on the skin:

In the surgical treatment of small areas of the skin, such as needle pricking and local lesions, 1 g/10 cm2 cream is applied as a thick layer and covered with a closed dressing. The dose should not exceed 1 g/10 cm2 and should be adjusted according to the applied area.

Newborns and infants under 3 months:

Apply a maximum of 1 g of cream to an area of maximum 10 cm2. The application time should not exceed 1 hour.

Babies 3-12 months old:

Apply a maximum of 2 g of cream to an area of maximum 20 cm2. Application time is 1 hour.

Children 1-6 years old:

Apply a maximum of 10 g of cream to an area of maximum 100 cm2. The application time is approximately 1 hour (maximum 5 hours).

Children 6-12 years old:

Apply a maximum of 10 g of cream to an area of maximum 100 cm2.

The application time is approximately 1 hour (maximum 5 hours).

- Application of JETEX® cream for some skin problems

A 30-minute application of JETEX® cream is recommended for removal of mollusca in children with atopic dermatitis.

- Application of JETEX® cream to the genital mucous membrane or genital skin

JETEX® cream should not be applied to the genital mucous membrane of children.

If you have the impression that the effect of JETEX® cream is too strong or weak, talk to your doctor or pharmacist.

If you used more JETEX® cream than you should:

Symptoms that may occur when you use a high amount:

Numbness on the lips and around the mouth, dizziness, vertigo and sometimes blurred vision. Even if there are no symptoms, if you used a large amount of JETEX® cream, contact your doctor or the emergency department of a health institution immediately. There is no toxic effect on doctor-recommended doses of the JETEX® cream.

When a large amount of JETEX® cream is used in combination with certain drugs, the risk of acute methemoglobinemia arises. Methemoglobinemia can be understood by the symptom of cyanosis (the skin acquires a gray-blue color). Such a condition can be cured by injection of methylene blue into the vein.

If you used more JETEX® cream than you should use, talk to a doctor or pharmacist.

If you forget to use JETEX® cream

If you forget to apply the cream on time, apply it as soon as you remember and then continue as before.

Do not take a double dose to make up for forgotten doses.

Effects that may occur when treatment with JETEX® cream is ended:

If you have any further questions on the use of this product, consult your doctor or pharmacist.

4. What are the possible side effects

Like all medicines, side effects may occur in people who are sensitive to the ingredients of JETEX® cream.

It may lead to cardiac dysrhythmia, respiratory distress, coma and even death, especially when applied to large skin surfaces and especially under occlusion.

JETEX® cream contains polyoxyethylene fatty acid ether. This may cause skin reactions.

"If any of the following occurs, stop using JETEX® cream and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:"

A mild reaction (redness of the skin or redness, slight swelling, initial burning or itching) may occur in the area where JETEX® cream is used. These are normal reactions to creams and anesthetics and disappear in a short time without any precautions. Allergic reactions as a result of using JETEX® cream (The most severe of these reactions is anaphylactic shock.) It can also be seen rarely in JETEX® cream.

If the following side effects occur and persist as a result of using JETEX® cream, contact your doctor. These reactions are usually for short-term and their effects decrease over time.

Side effects are listed as follows;

Very common : Can be seen in at least one in 10 patients.

Common : Less than one in 10 patients, but more than one in 100 patients.

Uncommon : Less than one in 100 patients, but more than one in 1,000 patients.

Rare : Less than one in 1,000 patients, but more than one in 10,000 patients.

Very rare : Less than one in 10,000 patients.

Unknown : It cannot be estimated from the available data.

If the following symptoms occur in you and if they persist, inform your doctor

Common side effects:

- Paleness, redness and swelling (edema) in the applied area.

- Mild burning, itching on the skin at the initial application

These are mild side effects of JETEX® cream and disappear in a short time.

Uncommon side effects:

- Mild burning, itching at the initial application (in the application area)

- Tingling in the application area

- Skin irritation (in the application area)

Rare side effects:

- Allergic reactions seen in local anesthetics (The most severe of these reactions is anaphylactic shock.) It can also be seen rarely in JETEX® cream.

- Methemoglobinemia (blue-gray coloration of the skin)

- Small red dots may be seen in the application area, especially in children with skin problems (atopic dermatitis or warts).

- Eye irritation may occur if JETEX® cream accidentally gets into contact with the eyes.

These are rare side effects of JETEX® cream. If you notice any of these effects, stop using JETEX® cream and tell your doctor immediately.

If you experience any side effects which is not mentioned in this directions for use, inform your doctor or pharmacist.

Reporting of side effects

Talk to your doctor, pharmacist or nurse in case of any side effects which are included or not included in the Directions for Use. Also, report the side effects you encounter to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effects Reporting" icon on www.titck.gov.tr or by calling the side effect reporting line at 0 800 314 00 08. By reporting the side effects that occur, you will contribute to obtaining more information about the safety of the medication that you are using.

5. Storage of JETEX® cream

Store JETEX® cream in places out of the reach of children and in its packaging.

Store JETEX® cream at room temperature below 25°C and in its original packaging.

Do not freeze the medication.

Use in accordance with the expiration date.

Do not use JETEX® cream after the expiration date on the packaging.

Do not use JETEX® cream if you notice defects in the product and/or its packaging.

Do not throw expired or unused drugs to trash! Give it to the collection system determined by the Ministry of Environment and Urbanization.

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This leaflet are approved on the date of.