

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

The medicine is dispensed without a doctor's prescription

Esracain[®] Cream 5%

Active ingredient:

Lidocaine 5%

1 gram cream contains 50 mg lidocaine (50 mg/g).

For the list of the additional ingredients, please see section 2 'Important information about some of the medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to the doctor or pharmacist.

Use the medicine according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you require additional information.

Refer to a doctor if the symptoms of the illness worsen or do not improve within 3-5 days (see section 2 'Additional warnings').

1. What is the medicine intended for?

The medicine is intended for topical anesthesia and local pain relief in the skin and mucous membranes, such as in cuts, scrapes and hemorrhoids and also before local skin treatments.

Therapeutic group: topical anesthetic of the amide group.

Background - Esracain Cream 5% belongs to a group of medicines called topical anesthetics, which blocks nerve signals, thereby causing a temporary lack of feeling in the area to which it is applied.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient, to another topical anesthetic of the amide group or to any of the additional ingredients the medicine contains (see section 6).
- You suffer from a blood disorder called methemoglobinemia.
- You suffer from glucose-6-phosphate dehydrogenase enzyme deficiency.
- In infants of 12 months of age or younger who are taking medicines that may cause methemoglobinemia (e.g. sulfonamides).

Special warnings concerning use of the medicine

Before the treatment with the medicine, tell the doctor if:

- You suffer or have suffered in the past from any health problems. A reduced dosage may be required.
- You suffer from heart and vascular problems, including:
 - Slow heart rate (bradycardia)
 - Irregular heartbeat (arrhythmia)
- You have suffered in the past from a severe, unusual or allergic reaction to Esracain Cream 5% or to any other medicines of the amide class.
- You think you may be sensitive or allergic to any ingredients in Esracain Cream 5%.
- You are sensitive to any medicine.
- You suffer from bleeding hemorrhoids and you want to use the cream in this area.
- You have an infection, skin rash, cut or wound at or near the area to which you want to apply the cream.
- You suffer from a skin problem that is severe or covers large areas of skin. Frequent use of the medicine, on large areas of skin or for a prolonged period, may cause the

appearance of serious side effects because of excessive absorption (see section 3 'Symptoms of overdose' and section 4 'Side effects').

- You suffer from liver or kidney problems.
- You suffer from epilepsy.
- You are experiencing severe shock.
- You are pregnant, plan a pregnancy, think you are pregnant or are breastfeeding.
- You are a geriatric patient (aged 65 or over).

Additional warnings

- Do not use this medicine frequently or for a prolonged period without consulting a doctor.
- Strictly follow the recommended dosage, especially in children, for whom the dosage varies according to weight. Use of a dose that is too high or too frequent may cause serious and even life-threatening side effects, including seizures, methemoglobinemia and loss of consciousness. See also section 'If you accidentally used a higher dosage'.
- Use the smallest amount necessary to control your symptoms.
- According to the dosage, topical anesthetics containing lidocaine may have a very moderate effect on mental functioning and there may be temporary impairment of movement and alertness.
- This medicine is not intended for use in the eyes. Avoid contact with the eyes (see section 3 'How to use the medicine').
- Refer to a doctor if the symptoms of the illness worsen or do not improve within 3-5 days.

Children

- Children are at greater risk for serious side effects. If the cream is prescribed by the doctor, strictly follow the instructions for use and the dosage as instructed by the doctor, especially in young children and babies.
- This medicine is not generally intended for babies under the age of two years .
- **Do not use the medicine on the genitals of children or babies.**

Elderly patients (age 65 and over)

Elderly patients may be more sensitive to systemic effects due to an increase in the blood lidocaine levels following repeated doses. A reduced dosage may be required.

Drug interactions

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist. Especially if you are taking:

- Medicines to treat heart rate disorders (e.g. mexiletine and amiodarone). The doctor will monitor you carefully and may send you for an electrocardiogram (ECG) if you are taking this medicine concurrently with amiodarone.
- Other topical anesthetics.
- Erythromycin for the treatment of bacterial infections.
- Itraconazole for the treatment of fungal infections.
- Propranolol for the treatment of heart problems, cimetidine for the treatment of gastrointestinal problems and fluvoxamine for the treatment of depression - if you are going to use high dosages of the cream for a prolonged period, there may be a drug interaction with concurrent administration of these medicines.
- Other medicines which may cause methemoglobinemia, including sulfonamides, acetanilide, aniline dyes, benzocaine or other anesthetics of the amide class, chloroquine, dapsone, naphthalene, nitrates or nitrites, nitrofurantoin, nitroglycerin, nitroprusside, pamaquine, para-aminosalicylic acid, phenacetin, phenobarbital, phenytoin, primaquine, quinine and high doses of acetaminophen.

Pregnancy and breastfeeding

Pregnancy

There is insufficient information on the effect of the active ingredient lidocaine on the development of the fetus. Do not use the medicine without consulting a doctor if you are pregnant, are planning a pregnancy or think you are pregnant, especially in the early stages of pregnancy.

Breastfeeding

The medicine passes into the breastmilk. Do not use the medicine without consulting a doctor if you are breastfeeding.

Driving and use of machinery

Know how you feel after using Esracain Cream 5% and employ suitable caution when driving or using dangerous machinery. In case of overdose there may be an effect on driving and use of machinery.

Important information about some of the medicine's ingredients:

Esracain Cream 5% contains cetyl alcohol, which may cause local skin reactions (for instance contact dermatitis).

Esracain Cream 5% contains methyl-hydroxybenzoate and propyl-hydroxybenzoate which may cause allergic reactions (possibly delayed), see section 4 'Side effects'.

3. How to use the medicine?

Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The standard dosage is usually:

This medicine is not generally intended for babies under the age of two .

In children from the age of two until the age of 12: do not apply more than 0.1 gram cream for every kg of body weight (application of approximately 3 cm cream for every 10 kg of body weight), up to 3 times daily (every 8 hours).

In adults and children over the age of 12: do not apply more than 5 grams cream (about 15 cm cream) once every six hours. Do not use more than one tube a day.

Do not exceed the recommended dose.

For persistent, severe or extensive skin problems, consult a doctor.

Manner of use:

Apply locally a thin layer to the affected area, as required. Do not bandage or heat the area.

Attention: do not swallow! This medicine is intended for external use only.

Avoid contact with the eyes. In case of contact with the eyes, rinse them thoroughly with water.

If you have accidentally taken a higher dosage: if you have applied an excessive amount or if a child has accidentally swallowed the medicine, refer immediately to a doctor or a hospital emergency room and bring the medicine package with you. Overdose symptoms may include (see also section 4 'Side effects'):

- Numbness of the lips, the tongue and around the mouth
- Feeling dizzy, lightheaded
- Vision disturbance, blurred vision
- Trembling
- Seizures, convulsions
- Loss of consciousness
- Changes in hearing and ringing in the ears (tinnitus)
- Changes in blood oxygen and carbon dioxide levels, interference with normal respiration and in severe cases, even respiratory arrest
- Severely low blood pressure, slow heart rate (bradycardia), irregular heartbeat (arrhythmia) and cardiovascular system collapse
- Methemoglobinemia
- Confusion
- Feeling hot, cold or numb

Do not take medicines in the dark! Check the label and the dose each time you take a medicine.

Wear glasses if you need them.

If you have further questions concerning the use of the medicine, consult the doctor or pharmacist.

4. Side Effects

As with any medicine, the use of Esracain Cream 5% may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop the treatment and refer to the doctor immediately if the following side effects appear:

- **Allergic reaction** (rare) (*appears in 1-10 users out of 10,000*), which includes symptoms such as: difficulty swallowing or difficulty breathing, wheezing, drop in blood pressure, nausea and vomiting, skin lesions, hives (urticaria) or rash, edema, swelling of the face, lips, tongue or throat and in severe cases, anaphylactic shock.
- **Methemoglobinemia** - blood disorder (rare) (*appears in 1-10 users out of 10,000*), which includes symptoms such as: brownish or grayish skin, especially around the lips and nails, paleness. Severe methemoglobinemia is associated with shortness of breath, rapid heart rate (tachycardia) and semi-consciousness.
- **Side effects** that may indicate excessive absorption (very rare) (*appear in less than one user out of 10,000*), which include: drowsiness, numbness in the tongue, lightheadedness, ringing in the ears, blurred vision, vomiting, dizziness, abnormally slow heart beat, fainting, nervousness, abnormal sweating, trembling or seizures. These symptoms will appear usually when large quantities of Esracain Cream 5% are applied for a prolonged time period.

Additional side effects

Esracain Cream 5% may cause local skin reactions (e.g. contact dermatitis) and allergic reactions (possibly delayed), (see section 2, 'Important information about some of the medicine's ingredients').

Side effects and drug interactions in children and babies:

Parents need to inform the attending doctor about any side effects and any additional medicine the child is taking. See 'Side effects' above and section 4 'Drug interactions' detailed.

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

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be stored in a safe place out of the reach and sight of children and/or babies, 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) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 25°C.

After the first opening, the cream may be used for 3 months, but no later than the expiry date imprinted on the package.

6. Additional information

- **In addition to the active ingredient, the medicine also contains:**

Emulsifying wax, glycerin, cetyl alcohol, lactic acid, propyl-hydroxybenzoate, methyl-hydroxybenzoate, purified water.

Every 1 gram Esracain Cream 5% contains 50 mg cetyl alcohol, 3 mg propyl-hydroxybenzoate and 2 mg methyl-hydroxybenzoate.

- **What does the medicine look like and what does the package contain?**

White cream packaged in an aluminum tube containing 20 gram.

Package contains one tube or 50 tubes.

Not all package sizes may be marketed.

7. Registration Holder and Manufacturer: Rafa Laboratories Ltd., PO Box 405, Jerusalem 9100301.

Medicine registration number in the National Medicines Registry of the Ministry of Health: 163027791

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