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

The medicine is dispensed without a doctor's prescription

Esracain® Gel

Active ingredient:
Lidocaine hydrochloride 2%
1 mL gel contains 20 mg lidocaine hydrochloride.
For the list of the additional ingredients, 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 this medicine according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you require additional information.
Refer to a doctor if the illness symptoms worsen or do not improve after 3 to 5 days.
The gel is not intended for relief of teething pains in children and babies.
The gel is not generally intended for children under 2 years of age and in any case children under 3 years of age should be treated under medical supervision only (see details below regarding use in children).

1. What is the medicine intended for?

The medicine is intended for topical anesthesia and topical relief of pain in the skin and mucous membranes. Do not use the medicine in sterile procedures.

Therapeutic group: topical anesthetic of the amide group.
Background - Esracain Gel belongs to a group of medicines called topical anesthetics, which block nerve signals, thereby causing temporary numbness 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 (lidocaine), prilocaine, another topical anesthetic of the amide group or to any of the additional ingredients the medicine contains (see section 6 'Additional information').
- Do not use in sterile procedures.
- 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 regarding the use of the medicine:

Before 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 Gel or to any other medicines of the amide group.

- You think you may be sensitive or allergic to any ingredients in Esracain Gel (section 2 'Important information about some of the medicine's ingredients' and section 6, 'Additional Information').
- You are sensitive to any food or medicine.
- You have an infection, skin rash, cut or wound at or near the area to which you want to apply the gel.
- You suffer from a skin problem that is severe or covers a large area of skin.
- You suffer from liver or kidney problems.
- You suffer from epilepsy.
- You or someone in your family has been diagnosed with a disorder that can cause nerve or skin problems (porphyria).
- You are experiencing shock.
- You are pregnant, are planning 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. Frequent use of the medicine, on large areas of skin or for a prolonged period, may cause side effects due to excessive absorption (see section 4 'Side effects').
- Strictly follow the recommended dosage, especially in children, in 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 3. 'If you accidentally used a higher dosage'.
- Use the smallest amount necessary to control the symptoms.
- Avoid contact of the medicine with the eyes (see section 3 'How to use the medicine?').
- 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.
- Topical anesthetics used in the mouth may numb the tongue and the mouth mucosa and make swallowing difficult. This can increase the risk of choking or accidentally biting the tongue or the inside of the cheeks. Do not eat or chew gum while the mouth is numb. Avoid very hot or very cold food and drinks until the numbness has worn off.

Children

- The gel is not intended for relief of teething pains in children and babies since it may cause serious side effects.
- The gel is not generally intended for children under 2 years of age and in any case children under 3 years of age should be treated under medical supervision only.
- Children are at greater risk for serious side effects. It is important to always adhere to the instructions for use and the dosage, since swallowing the gel and not adhering to the instructions for use and the dosage could cause serious and life-threatening effects (e.g. seizures). If the gel is prescribed by the doctor, strictly adhere to the instructions for use and the dosage as instructed by the doctor, especially in young children and infants.
- **Do not use the medicine on the genitals of children or babies.**

Elderly patients (aged 65 and over)

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

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 heartbeat disturbances (anti-arrhythmic medicines), e.g. mexiletine, amiodarone. The doctor will monitor you carefully and may refer 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 gel for a prolonged period, there may be an interaction in concurrent administration of these medicines.
- Other medicines which may cause methemoglobinemia, including: sulfonamides, acetanilide, aniline dyes, benzocaine or other anesthetics of the amide group, chloroquine, dapsone, naphthalene, nitrates or nitrites, nitrofurantoin, nitroglycerin, nitroprusside, pamaquine, para-aminosalicylic acid, phenacetin, phenobarbital, phenytoin, primaquine, quinine and high doses of acetaminophen.

Use of the medicine and food
If the gel is used in the mouth cavity - do not eat or chew gum while the mouth is numb. Avoid very hot or very cold food and drinks until the numbness has worn off (also see 'Additional warnings' above).

Pregnancy and breast-feeding
Pregnancy
There is insufficient information on the effect of the active ingredient lidocaine on 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
Do not use the medicine without consulting a doctor before starting the treatment if you are breastfeeding. The medicine passes into the breastmilk. Do not apply to the breast since the baby may swallow the medicine with the milk.

Driving and use of machinery
Know how you feel after using Esracain Gel 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 Gel contains propylene glycol and benzalkonium chloride which may irritate your skin.

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:
Dosage for adults (over 18 years of age)
Use the smallest amount necessary to control your symptoms.

- Usually the effective dose is no more than 5 to 10 mL per application.
- Do not use more than 6 doses a day (24 hours).

Dosage for children:
The gel is generally not intended for children under 2 years of age and in any case children under 3 years of age should be treated under medical supervision only.
If the doctor instructed the use of the gel for a child under 2 years of age, do not use for longer than one day (24 hours).

Dosage for children weighing less than 50 kg (and over 2 years of age)

- The dose depends on the child's weight. Use the smallest amount necessary to control the symptoms.
- For each dose do not use more than 1 mL for every 5 kg of body weight. Do not exceed a maximum dose of 10 mL per application. For instance: a child weighing 25 kg can use a maximum of 5 mL of gel in each dose.
- Do not use more than 4 doses a day (24 hours). The gel can be applied once every six hours.

Dosage for children weighing more than 50 kg:

- Use the smallest amount necessary to control the symptoms.
- Usually the effective dose is no more than 5 to 10 mL per application.
- Do not use more than 4 doses a day (24 hours). The gel can be applied once every six hours.

Do not exceed the recommended dosage.

Duration of treatment
If there is no improvement in your condition within 3 to 5 days or if there is any deterioration, refer to the doctor.

Manner of use

- **Attention!** Do not swallow! The gel is intended for topical use only.
- Not for use in sterile procedures.
- For use on the skin, the mucous membranes and in the oral cavity.
- Apply the gel with a clean finger, a Q-tip or a piece of gauze.
- Wash your hands after use.
- Avoid contact with the eyes.

These guidelines indicate the recommended dosage for use if you are using the medicine without medical supervision. The recommendations are intended for healthy patients.
If the gel is prescribed for you by the doctor, strictly adhere to the instructions for use and the dosage as instructed by the doctor.

If you have accidentally taken a higher dosage: if you have applied an excessive amount or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room for fear of excessive absorption, 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
- Visual 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, breathing disturbances 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

A serious overdose must be treated immediately, since it could be life-threatening.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> 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. <u>Side Effects</u>

As with any medicine, the use of the gel 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.

Stop treatment and refer to a 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), itching 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 rate, fainting, nervousness, abnormal sweating, trembling or seizures. These symptoms may appear when using an excessively high dosage of the gel at one time and with use of a high dosage of the gel for a prolonged period.

  A serious overdose must be treated immediately, since it could be life-threatening (see also section 3 'If you accidentally took an overdose').

Side effects and drug interactions in children:
Parents must inform the attending physician of any side effect and of any other medicine given to the child. See 'Side effects' above and section 4 'Drug interactions' listed.

If a side effect appears, if one of the side effects worsens, or if 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, it may be used for 6 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 the following inactive ingredients:**
  Glycerin anhydrous, propylene glycol, hydroxyethyl cellulose, benzalkonium chloride, sodium hydroxide, purified water.

  Every 1 mL of Esracain Gel contains approximately 20 mg propylene glycol and 0.15 mg benzalkonium chloride.

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

Transparent, colorless gel, packed in an aluminum tube containing 30 gram.

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

Medicine registration number in the National Medicines Registry of the Ministry of Health: 192621043

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