

Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold without a doctor's prescription

ESRACAIN GEL

Active ingredient: Lidocaine hydrochloride 2%

For the list of inactive ingredients, please see section 6.

Read this entire leaflet carefully before using this medicine.

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

Refer to your doctor if the symptoms get worse or do not improve after 3-5 days.

The gel is not intended for relieving teething pains in children and infants.

The gel is usually not intended for children under the age of 2 years and in any case children under the age of 3 will be treated under medical supervision only (see details below on use in children).

Use this medicine in the correct manner. Consult the pharmacist if you need additional information.

1. What is the medicine intended for?

This medicine is intended for use as a topical anesthetic for local relief of pain of the skin and mucous membranes. Do not use this medicine in sterile procedures.

Therapeutic group: Local anesthetic of the amide group.

2. Before using the medicine

Do not use the medicine if:

- Do not use if you are sensitive (allergic) to the active ingredient, to any other local anesthetic of the amide group, or to any of the other ingredients the medicine contains (for the list of inactive ingredients, please see section 6).
- Do not use in sterile procedures.
- Do not use on festering sores or large areas of skin. Frequent use of this medicine, on large areas of skin or for a long period may cause side effects due to excessive absorption (see section 'side effects').

Special warnings regarding the use of this medicine:

- Do not use this medicine frequently or for a long period without consulting a doctor.
- The recommended dosage should be strictly adhered to. Use of a too high or too frequent dosage, may cause serious and even life-threatening side effects, including seizures and loss of consciousness. See also 'If you have accidentally used a higher dosage' section.
- If you are sensitive to any type of food or medicine, inform your doctor before using this medicine.
- If the gel is used inside the oral cavity – do not chew (including chewing gum), eat or drink for at least one hour after the application. Numbness in the oral cavity and the throat can interfere with swallowing and cause choking. Numbness of the tongue and the gums may cause injury as a result of biting.
- Avoid exposure to very hot or very cold temperatures (e.g. eating, drinking or touching) until sensation fully returns.
- Patients suffering from shock - will be treated only under medical supervision.

Do not use this medicine without consulting a doctor before starting treatment, in the following cases:

- If you are pregnant, planning to become pregnant or breastfeeding.
- If you suffer or have suffered in the past from epilepsy.
- If you suffer or have suffered in the past from impaired function of the: liver, kidneys, heart.

- If you suffer from persistent, severe or extensive skin problems.
- If the skin at the application area is wounded, inflamed, infected or has a rash.
- If you are elderly or suffer from any acute illness.
- If you or one of your family members suffer from porphyria (hereditary disease in which there is an increased production and accumulation of porphyrin, which causes dermal or nervous system disorders).

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist.

Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list mentions the active ingredients of the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist).

- Medicines for treatment of heart and blood vessel diseases, e.g.: propranolol or medicines for treatment of heart rhythm disturbances (e.g. anti-arrhythmic medicines such as mexiletine, amiodarone).
- Other anesthetics.
- Cimetidine (for treatment of problems in the digestive system), fluvoxamine (for treatment of depression): the combination can interfere mainly while using a high dosage of the gel (on large areas of skin and with high frequency) and/or for a long period.

Using this medicine with food:

If the gel is used inside the oral cavity – do not chew (including chewing gum), eat or drink for at least one hour after the application. See also warnings above.

Pregnancy and breastfeeding:

Do not use the medicine without consulting a doctor before starting treatment, if you are pregnant, planning a pregnancy or breastfeeding.

Use in Children:

- The gel is not intended for relieving teething pains in children and infants since it may cause serious side effects.
- The gel is usually not intended for children under the age of 2 years and in any case children under the age of 3 will be treated under medical supervision only.
- The dosage and instructions for use must be carefully followed since swallowing of the gel and failure to follow the instructions for use and the dosage may cause serious side effects (e.g. seizures) and life-threatening side effects.

3. How to use this medicine?

- **Attention!** Not to be swallowed! The gel is intended for topical use only.
- Not to be used in sterile procedures.
- For use on the skin, mucous membranes and oral cavity.
- Apply the gel using a clean finger, a cotton swab or a piece of gauze.
- Wash your hands after use.
- Avoid contact with the eyes.

The standard dosage is usually:

Dosage for adults (over the age of 18):

Use the smallest amount necessary to control your symptoms.

- Usually the effective dose is no more than 5 to 10 mL per application.

- No more than 6 doses should be used per day (24 hours).

Dosage in Children:

The gel is usually not intended for children under the age of 2 years and in any case children under the age of 3 will be treated under medical supervision only.

If the doctor instructed using the gel on a child under the age of 2 years, do not use for more than one day (24 hours).

Dosage in children weighing less than 50 kg (and over the age of 2 years):

- The dosage 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 in each application. E.g.: for a child weighing 25 kg a maximum of 5 mL of gel can be used in each dose.
- No more than 4 doses should be used per day (24 hours). The gel can be applied once every six hours.

Dosage in Children weighing over 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.
- No more than 4 doses should be used per day (24 hours). The gel can be applied once every six hours.

Do not exceed the recommended dose.

These instructions indicate the recommended dosage for use if you are using the medicine without medical supervision. The recommendations are intended for healthy patients.

If your doctor prescribed the gel for you, you must strictly adhere to the instructions for use and the dosage as instructed by your doctor.

You should check with your doctor or pharmacist if you are not sure.

Refer to your doctor if there is no improvement in your condition within 3-5 days or if there is a deterioration in your condition.

If you have accidentally used a higher dosage or if you or a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room for fear of excessive absorption, and bring the package of the medicine with you. Signs of excessive absorption include inter alia: excessive sweating, vomiting, dizziness, sensation of heat/cold, tingling, restlessness, drowsiness, slow or irregular heartbeats, decrease in blood pressure, changes in vision or hearing (e.g. blurred vision, ringing in the ears), confusion, tremor, twitching, seizures, breathing difficulties, fainting, loss of consciousness. A severe overdose must be treated immediately since it may be life-threatening. See also section 'side effects'.

Do not use or 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 any further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of the gel may cause side effects in some users. If these side effects persist or are bothersome or get worse, please consult your doctor. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop the treatment and refer to the doctor immediately in the following cases:

- Upon the occurrence of an allergic reaction including symptoms such as: skin problems, for instance redness, itching or swelling of skin; urticaria; burning, stinging; swelling of the neck, breathing difficulties.
- Upon the occurrence of local irritation, rash or inflammation (that did not exist prior to the use of this medicine).
- If you feel symptoms of excessive absorption, which include: excessive sweating, vomiting, dizziness, light-headedness, sensation of heat /cold or tingling, numbness, restlessness, drowsiness, slow or irregular heartbeats, decrease in blood pressure, changes in vision or hearing (e.g. blurred vision, ringing in the ears), confusion, tremor, twitching, seizures, breathing difficulties, fainting, loss of consciousness. A severe overdose must be treated immediately since it may be life-threatening. These symptoms are extremely rare, and usually can happen when a high dosage of the gel is used and/or the gel is used for a long period.

Side effects and drug interactions in children:

Parents must inform the attending doctor about any side effect as well as any additional medicine given to the child. See above for detailed side effects and drug interactions.

If you experience any side effects that are not mentioned in this leaflet or if there is any change in your general feeling, consult the doctor immediately!

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, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a 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 first opening of the tube, the gel may be used within 6 months, but no later than the expiry date marked on the package.

6. Additional information

In addition to the active ingredient, this medicine also contains the following inactive ingredients:

Glycerin, hydroxyethyl cellulose, propylene glycol, benzalkonium chloride, sodium hydroxide, water.

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

Transparent and watery gel in an aluminum tube.

Registration holder: Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301.

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

This leaflet was checked and approved by the Ministry of Health in March 2015.