

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

**This medicine is dispensed without a doctor's prescription**

## **LIDOCAINE RAZ GEL 2 %**

### **Active ingredient:**

Lidocaine hydrochloride 2%  
Each 1 gram (1ml) of gel contains 20mg of Lidocaine hydrochloride.

Inactive ingredients and allergens in the medicine – see section 6 'additional information' and in section 2 'Important information about some of the ingredients of this medicine'.

### **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.

You should use the medicine according to the instructions in the section about dose in this leaflet – section 3 'How to use this medicine?'.  
Consult the pharmacist if you need additional information.

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

### **1. What is the medicine intended for?**

The medicine is intended for local anesthesia. Not to be used for procedures requiring sterile medicines.

**Therapeutic group:** Local anesthetic from the amide group.

**Background:** Lidocaine Raz Gel 2% Belongs to a group of drugs called local anesthetics, which block nerve signals and thus cause temporary numbness in the area where it is applied.

### **2. Before using the medicine**

**Do not use the medicine if:**

- Do not use if you are sensitive (allergic) to the active ingredient (Lidocaine Hydrochloride), Prilocaine, any other local anesthetic of the amide group, or to any of the other 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 a deficiency in the enzyme glucose 6-phosphate dehydrogenase.
- In infants 12 months of age and younger who are taking medications that may cause methemoglobinemia (such as: sulfonamides).

### **Special warnings regarding the use of this medicine:**

**Before treating with Lidocaine Raz Gel 2% with the drug, tell the doctor if:**

- You suffer or have suffered in the past from any health problems. A reduced dose may be required.
- You suffer from heart and blood vessel problems, including:
  - Slow heart rate (bradycardia).
  - Abnormal heart rhythm (arrhythmia).
- You have suffered in the past from a severe, unusual or allergic reaction to **Lidocaine Raz Gel 2%** or to other medicines from the amide group.
- You think you may be sensitive or allergic to any of the ingredients in **Lidocaine Raz Gel 2%** (see section 2 - 'Important information about some of the ingredients of this medicine' and section 6 - 'Additional information').
- You are sensitive to any type of food or medicine.
- You have an infection, skin rash, cut or wound in or near the area where you want to apply the gel.
- You suffer from a skin problem that is severe or covers large areas of skin.
- You suffer from liver or kidney problems.
- You suffer from epilepsy.
- You or one of your family members has been diagnosed with a disorder that may cause nervous system problems or skin problems (porphyria).
- You experience shock.
- You are pregnant, planning a pregnancy, think you are pregnant or breastfeeding.
- You are an elderly patient (age 65 or older).

### **Additional warnings**

- Do not use this medicine frequently or for a long period without consulting a doctor. Using the medicine frequently, on large areas of skin or for a prolonged period, may cause side effects due to excessive absorption (see section 4 - 'Side effects').
- The recommended dosage must be adhered to, especially in children, where the dosage varies according to weight. Using a dose that is too high or too frequent may cause serious and even life-threatening side effects, including convulsions, methemoglobinemia and loss of consciousness. See also section 3 - 'If you accidentally used a higher dose'.
- Use the smallest amount necessary to control symptoms.
- Contact of the medicine with the eyes should be avoided (see section 3 - 'How to use this medicine?').
- Depending on the dosage, local anesthetics containing lidocaine may have a very mild effect on mental function and may temporarily impair movement and alertness.
- When used inside the oral cavity, local anesthetics may cause numbness in the tongue and oral mucosa and make swallowing difficult. This may 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 anesthetized. Avoid very hot or very cold foods and drinks until the numbness goes away.

### **Children and Adolescents:**

- 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.
- Children are at increased risk of serious side effects. It is always important to follow the instructions for use and dosage, since swallowing the gel and not following the instructions for use and dosage may cause serious side effects (such as convulsions) and be life-threatening. If the gel is prescribed by the doctor, you must follow the instructions for use and dosage as ordered by the doctor, especially in young children and infants.
- **Do not use the medicine on the genitals of children or infants.**

### **Elderly (age 65 and over)**

Elderly patients may be more sensitive to systemic effects due to increased blood levels of lidocaine following repeated doses. A dose reduction may be required.

### **Drug interactions**

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

**Particularly if you are taking:**

- Medicines for the treatment of heart rhythm disorders (antiarrhythmic drugs) such as mexiletine, amiodarone. The doctor will monitor you carefully and you may be referred for an electrocardiogram (ECG) test if you are taking this medicine together with amiodarone.
- Other local anesthetics.
- Erythromycin to treat bacterial infections.
- Itraconazole to treat 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 doses of the gel for a long period of time, there may be an interaction in combined administration with these medicines.
- Other medicines that may cause methemoglobinemia, including: sulfonamides, acetanilid, aniline dyes, benzocaine or other amide-type anesthetics, chloroquine, dapsone, naphthalene, nitrates or nitrites, nitrofurantoin, nitroglycerin, nitroprusside, primaquine, para-aminosalicylic acid, phenacetin, phenobarbital, Phenytoin, primaquine, quinine, and high doses of acetaminophen.

### **Using this medicine with food:**

In case the gel is used in the oral cavity - do not eat or chew gum while the mouth is anesthetized. Very hot or very cold foods and drinks should be avoided until the numbness has passed (see also 'Additional warnings' above).

### **Pregnancy and breastfeeding**

#### **Pregnancy**

There is insufficient information regarding the effect of the active ingredient lidocaine on fetal development. Do not use the medicine without consulting a doctor if you are pregnant, 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 treatment if you are breastfeeding. The medicine passes into breast milk. Do not apply on the chest because the infant may swallow the medicine with the milk.

### **Driving and using machines**

You should know how you feel after using **Lidocaine Raz Gel 2%** and take proper care when driving or using dangerous machinery. In case of an overdose, driving and using machines may be affected.

### **Important information about some of this medicine's ingredients**

Each 1 gram of **Lidocaine Raz Gel 2%** contains 0.61 mg of

methyl-para-hydroxy-benzoate and 0.27 mg of propyl-para-hydroxy-benzoate. methyl-para-hydroxy-benzoate and propyl-para-hydroxy-benzoate may cause an allergic reaction (possibly delayed) (see also section 4 - 'Side effects').

### **3. How to use this medicine?**

You must Check with your doctor or pharmacist if you are not sure about the dose or how to take this medicine.

### **The usual dose is:**

#### **Dosage for adults (over the age of 18):**

Use the smallest amount necessary to control your symptoms.

- Usually, the effective dose is not more than 5 to 10 ml per application.
- Do not use more than 6 doses a 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 not 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 dose.**

### **Treatment duration**

If there is no improvement in your condition within 3 to 5 days or if there is a worsening, you should contact your doctor.

### **Method of administration**

#### **• 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.

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.

### **If you have accidentally used a higher dosage**

If you applied too much or a child accidentally swallowed some medicine, immediately go 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 in the lips, tongue and around the mouth.
- Feeling dizzy, dizziness.
- Visual impairment, blurred vision.
- Tremors.
- Convulsions, twitching.
- Loss of consciousness.
- Changes in hearing and ringing in the ears (tinnitus).
- Changes in the level of oxygen and carbon dioxide in the blood, breathing disturbance and even respiratory arrest, in severe cases.
- Severely low blood pressure, slow heart rate (bradycardia), irregular heart rhythm (arrhythmia) and collapse of the cardiovascular system.
- Methemoglobinemia.
- Confusion.
- Feeling hot, cold or numb.

### **A severe overdose must be treated immediately, as it can be life-threatening.**

**Do not take medicines in the dark! Check the label and 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 with any medicine, the use of **Lidocaine Raz Gel 2%** 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 use and contact your doctor immediately if the following side effects appear:**

- **Allergic reaction** (rare) (appears in 1-10 users out of 10,000), including 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, an anaphylactic shock.
- **Methemoglobinemia** - a blood disorder (rare) (occurs in 1-10 users out of 10,000), which includes symptoms such as: skin with a brown or grayish tint, especially around the lips and nails, skin paleness.  
Severe methemoglobinemia is associated with shortness of breath, rapid heart rate (tachycardia) and blurring of consciousness.
- Side effects that may indicate excessive absorption (very rare) (occurring in less than 1 user in 10,000), including: drowsiness, numbness of the tongue, feeling of dizziness, ringing in the ears, blurred vision, vomiting, dizziness, abnormally slow pulse, fainting, nervousness, abnormal sweating, tremors, or convulsions. These symptoms may appear if the gel is used in too high dose at one time and if the gel is used in a high dose for an extended period of time.

### **A severe overdose must be treated immediately as it may be life-threatening (see also section 3 – 'If you have accidentally used a higher dosage').**

### **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 section 2- 'Drug interactions'.

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

### **Reporting of side effects**

Side effects can be reported to the Ministry of Health by clicking the link 'Report side effects due to medication' that can be found on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to an online form for reporting side effects, or by clicking 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 closed place out of the reach and sight of children and/or infants 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 temperature of 25°C.
- **After the first opening:** the medicine can be used for 12 months when the medicine is stored at a temperature below 25°C, but no later than the expiration date printed on the package.

### **6. Additional information**

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

Hydroxypropyl methylcellulose (HPMC), Methyl p-hydroxybenzoate, Propyl p-hydroxybenzoate, Sodium hydroxide, Hydrochloric acid, Purified water.

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

An aluminum tube containing 30 grams of transparent or almost transparent gel.

### **Marketing authorization holder and importer:**

RAZ pharmaceuticals LTD., 31 GESHER HAETZ ST., INDUSTRIAL PARK, EMEK HEFER, 3877701, ISRAEL

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

175-25-36374-00.

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