

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

Please read the entire leaflet carefully before using this medicine

## ESRACAIN Cream

### Composition:

Active ingredient Lidocaine 5%

### Inactive ingredients

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

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

**Therapeutic activity:** This medicine is indicated as a topical anesthetic and as local pain relief of the skin and mucous membranes, due to cuts, abrasions and hemorrhoids and before local skin procedures.

### When should this medicine not be used?

Do not use this medicine if you are hypersensitive to any of its ingredients, or to another local anesthetic of the amide group.

Do not use on festering sores, open wounds, burns or large areas of skin. Frequent usage of this medicine on large skin areas or for a long period of time, including use before cosmetic procedures, may result in severe side effects due to excessive absorption. Those effects are detailed below in the side effects section.

This medicine is not intended for use in the eyes.

**Do not take this medicine without consulting a doctor before starting treatment, in the following cases:** If you are pregnant or breastfeeding. If you suffer or have suffered in the past from impaired function of the: liver, kidneys, heart and/or vascular system, or if you are a geriatric patient.

### Warnings:

Do not take this medicine frequently or for a long period without consulting your doctor.

If you are sensitive to any type of food or medicine, inform your doctor before starting treatment with this medication.

### Drug interactions:

If you are taking any other medications including non-prescription drugs and nutrition supplements, or if you have recently finished treatment with another drug, please notify your doctor in order to prevent any potential risks or a potential reduction in efficacy that may result from drug interactions. In particular, medicines of the following therapeutic groups may interact with your medicine: medications for the treatment of heart diseases/hypertension, cimetidine, other local anesthetics.

### Side effects:

In addition to the desired effect of the medicine, side effects may also appear during the course of taking this medicine.

If these side effects persist and/or are bothersome, please consult your doctor.

### The following side effects require special attention:

Local irritation, rash or infection (that did not exist prior to the use of this medicine) (rare): Stop the treatment and refer to your doctor immediately! Signs of excessive absorption - excessive sweating, pale skin, slow or irregular heartbeat, breathing difficulties, changes in vision or hearing,

confusion, spasms, dizziness, sensation of heat, cold or numbness, tremors, hyper vigilance, drowsiness: Stop the treatment and refer to your doctor immediately!

In use for hemorrhoids - if there is no improvement within 7 days or if deterioration occurs, consult your doctor.

If at any time you experience side effects that are not mentioned in this leaflet or if you feel an adverse change in your general health, consult your doctor immediately!

### Side effects and drug interactions in children and infants:

Parents must inform the doctor about any side effects, as well as any additional medicine being taken by the child.

See above for details of side effects and drug interactions.

### Recommended dosage unless otherwise prescribed by your doctor:

This medicine is usually not intended for infants under the age of two years.

Children 2-12 years of age: do not apply more than 0.1 grams of cream for each kg of body weight (application of approximately 3 cm of cream for each 10 kg of body weight), up to 3 times per day (every 8 hours).

Adults and children over 12 years of age: do not apply more than 5 grams of cream (approximately 15 cm of cream) once every 6 hours. Do not use more than one tube per day.

Do not exceed the recommended dose.

For persistent, severe or extensive skin conditions, consult your doctor.

### 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 well with water.

### Directions for use:

Apply topically in a thin layer to the affected area, as needed. Do not bandage or heat the area.

### Avoid poisoning!

This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning.

If you or a child have/has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Do not induce vomiting unless explicitly instructed to do so by a doctor!

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

Wear your glasses if you need them.

**Storage:** This medicine should be stored below 25°C.

Even if stored properly according to the manufacturer's recommendations, all medicines have a limited shelf life. Please pay attention to the expiry date of your medicine! If you have any doubts, please consult the dispensing pharmacist.

Do not store different medicines in the same container.

**Drug registration number:** 163027791



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