PACKAGE LEAFLET: Information for the patient

LIDOKAINE

Solution for injection – 2% (20 mg / ml)

(Lidocaine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious or if you notice side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. WHAT LIDOKAINE IS AND WHAT IT IS USED FOR

Lidocaine is a local anaesthetic of the amide type and an antiarrhythmic of the class I b. Lidocaine decreases the permeability of the neuronal cell membrane to Na^+ ions and binds competitively to calcium ions. Thus, lidocaine inhibits the signal generation and conduction in all types of sensory, motoric and autonomic nerves; this action is reversible. The antiarrhythmic action of lidocaine consists in shortening the refractory period of Purkinje fibers, inhibiting the electric activity of depolarized arrhythmogenic tissues. Consequently, lidocaine is effective in arrhythmias associated with depolarization, for example during glycoside intoxication and ischemias.

Lidocaine is ineffective when given orally, but it is effective when given parenterally. During local anaesthesia, it is rapidly absorbed from the injection site and it is a local anaesthetic with a rapid onset of action, intermediate duration (about 1.5 hours) and low toxicity. Peak plasma concentration is achieved after 30 minutes to 2 hours after intramuscular injection. Therapeutic levels of lidocaine in arrhythmias vary between 1.5 mcg / mL to 6 mcg / mL. Plasma levels higher than 4 mcg / mL are associated with toxic effects including dizziness and drowsiness.

Lidokaine solution for injection is indicated in the following conditions:
as a local anesthetic in peripheral and locoregional anesthesia; ventricular arrhythmia, especially after myocardial infarction.
Your doctor may have prescribed Lidokaine for another reason. Ask your doctor if you want to know why you are taking this medicine.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LIDOKAINE

Do not take Lidokaine if you have:

- hypersensitivity (allergy) to local anaesthetics of the amide type (including lidocaine) or to any of the excipients of Lidokaine;
- Stokes-Adams or Wolff-Parkinson-White syndrome;
- atrioventricular block or other heart conduction disturbances;
- hypovolemia;
- sinoatrial disorders or severe myocardial depression;
- porphyria.

Take special care with Lidokaine

Talk to your doctor before taking Lidokaine.
Lidocaine, like other local anaesthetics, should be used with caution in the elderly, debilitated patients, children, in patients with epilepsy, congestive heart failure, myasthenia gravis, shock, bradycardia, impaired cardiac conduction, impaired respiratory or liver function (lidocaine is not metabolized as usual in patients with hepatic impairment, therefore, toxic plasmatic concentrations may occur). Lidocaine and its metabolites may accumulate in patients with renal impairment.

Lidocaine should also be used with caution in patients with cardiovascular function impairment, because these patients are less capable to compensate for functional changes associated with QT interval prolongation caused by this drug.
When used as an antiarrhythmic in the elderly and patients with cardiac insufficiency, cardiogenic shock, or liver disease, lidocaine dose should be reduced (up to 50% of the usual dose) and the rate of infusion should be reduced.
Careful electrocardiographic monitoring of the patient should be performed during lidocaine intravenous injection and all the necessary equipment to treat any unwanted effects that may occur, should be available.
Caution should be taken in patients who have low concentration of potassium in the blood causing muscle cramps, constipation (hypokalaemia).
If the injection is performed in an inflamed or infected site, the effect of the local anaesthetic may decrease and there is a risk for systemic side effects.
Patients with arrhythmia should be treated with lidocaine only (lidocaine without adrenaline), whereas lidocaine with adrenaline is used only during local anaesthesia.
Lidocaine should not be used in pregnancy, except in cases where it is clearly needed.

Other medicines and Lidokaine
Concomitant therapy with other medicines can affect or can be affected by Lidokaine.
Tell your doctor or pharmacist if you are taking or have recently taken any other medicine, including those obtained without a prescription. Do not forget to inform your doctor about your treatment with Lidokaine if you are prescribed any other medicines during treatment.
Concomitant use of lidocaine and other antiarrhythmics can increase the depressive effect of lidocaine in the heart.
Cimetidine and beta-blockers enhance the effect of lidocaine by depressing the enzyme system of the liver. There is an increased risk of lidocaine toxicity when given with propranolol.
Lidocaine is predicted to increase the effects of muscle relaxants (e.g. suxamethonium).
Concomitant use of opioids, strong pain relieving medicines (e.g. fentanyl) and lidocaine might increase the risk of CNS depressant effects, such as drowsiness, which might affect the ability to perform skilled tasks.

Long-term treatment with medicines that promote the liver enzyme activity such as barbiturates, benzodiazepines and phenytoin, may require an increase in the dosage of lidocaine.
The effect of lidocaine is antagonized from hypokalemia caused by acetazolamide, loop diuretics, or thiazide and related diuretics.
The risk of ventricular arrhythmias is increased when antiarrhythmics that prolong the QT interval are given with antipsychotics that prolong the QT interval.
Plasma concentration of lidocaine is possibly increased by atazanavir, lopinavir, darunavir and fosamprenavir. Avoid concomitant use of lidocaine with fosamprenavir.
The risk of ventricular arrhythmias is increased when lidocaine is given with saquinavir — avoid concomitant use.

Pregnancy

Ask your doctor or pharmacist for advice before taking this medicine!
Lidocaine should not be used in pregnancy, unless it is strictly necessary.

Lactation

Lidocaine is excreted in breast-milk, but the amount is too small to be harmful. Ask your doctor or pharmacist for advice before using this drug.

Driving and using machines

Lidocaine may impair the ability of the patient to drive or use machines.

Important information about some of the excipients of Lidokaine

Lidokaine contain less than 1 mmol sodium (23 mg) per 1 ml, that is to say essentially ‘sodium-free’.

3. HOW TO TAKE LIDOKAINE

This medicine will be administered by a doctor or specialized medical personnel. If you notice that the effects of Lidokaine are too weak or too strong, contact your doctor or pharmacist.

In local peripheral and locoregional anesthesia: Doses should be adjusted according to the type of procedure, site of injection and response of the patient. The maximum dose is 200 mg. Children, elderly and debilitated patients should use lower doses.
Lidokaine should only be administered by, or under the supervision of, doctors experienced in local anesthesia and resuscitation techniques. When local anesthetics are administered parenterally, resuscitation equipments should be available.

As an antiarrhythmic: An intravenous dose of 50 to 100 mg is recommended. The initial dose of 25 – 50 mg/min may be repeated after 5 minutes. *By intravenous infusion,* the recommended dose is 20 – 50 mcg / kg up to 1 – 4 mg / min; the maximum dose is 300 mg, whereas doses of 30 mcg / kg body weight / min. are recommended for children.
By intramuscular injection (deltoid muscle) a dose of 4 to 5 mg / kg body weight is recommended. This dose may be repeated if necessary after 60 to 90 minutes, up to a maximum dose of 300 mg in 1 hour. However, this route should be used as an alternative of the intravenous route in cases when the electrocardiographic monitoring of the patient is not possible.
In the elderly or patients with cardiac failure, cardiogenic shock or hepatic impairment, the dose of lidocaine should be reduced (up to 50 % of the usual dose) and the rate of infusion should also be decreased to 1 – 2 mg / min.

If you take more Lidokaine than you should

If you have taken too much Lidokaine, or if the children have taken this medicine by accident, always contact a doctor or hospital or call the emergency for advice and evaluation of the risk. Overdosage can result in severe hypotension, asystole, bradycardia, apnea, seizures, coma, cardiac arrest, respiratory arrest and death. The treatment is symptomatic. Treatment objectives are to maintain oxygenation and circulation, and stop the convulsions.
If you have further questions regarding the use of this medicinal product, ask your doctor or

pharmacist.

4. POSSIBLE SIDE EFFECTS

As with other local anaesthetics, side effects of lidocaine are rare and are usually the result of high plasma concentrations, excessive dosage or rapid absorption, or may result from hypersensitivity, idiosyncrasy or diminished tolerance of the patient. Systemic toxicity mainly involves the central nervous system and/or the cardiovascular system.
Central nervous system reactions may be excitatory and/or depressant and may manifest as nervousness, paresthesia, tinnitus, nausea, vomiting, muscle twitching, numbness of the tongue and perioral region, dizziness, blurred vision, transient excitation and tremor followed by drowsiness, convulsions, unconsciousness, possibly respiratory arrest and coma. The excitatory reactions may be brief or may not occur at all.
Cardiovascular reactions are of depressing character and may manifest as hypotension, myocardial depression, bradycardia, and possibly cardiac arrest.
Eye disorders which are shown as blurred vision or double vision.
It may cause breathing disorders as finding difficult to breathe or the breathing may stop.
Allergic reactions are rare. They may be characterized by cutaneous lesions, urticaria, oedema or anaphylactoid reactions.

If any of the side effects worsens or if you have side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects:
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to the Pharmacovigilance Department of the National Agency of Drugs and Medical Devices at the email address farmakovigjilenca@akbpm.gov.al or via the website www.akbpm.gov.al/formulari-raportimi. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LIDOKAINE

Keep the medicine out of the sight and reach of children!

Do not use this medicine after the expiry date which is stated on the packaging.

Do not store above 25°C!

Store in the original packaging to protect it from light.

6. OTHER INFORMATION

What Lidokaine solution for injection 2% contains

The active substance is lidocaine hydrochloride.

1 ml of solution for injection contains 20 mg lidocaine hydrochloride (2%).

The excipients are: sodium chloride, sodium hydroxide, water for injection.

Contents of the pack

Box with 10 ampoules of 2 ml

Box with 1 glass bottle of 50 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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