PACKAGE LEAFLET: Information for the user

LIDOKAINE ME ADRENALINE

Solution for injection

(1000 mg + 0.5 mg) / 50 ml

(Lidocaine hydrochloride, Adrenaline (as hydrogentartrate))

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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

1. WHAT LIDOKAINE ME ADRENALINE IS AND WHAT IT IS USED FOR

Lidocaine belongs to the group of local anaesthetics of the amide type. Lidocaine alters signal conduction in neurons by blocking the fast voltage gated sodium (Na^+) channels in the neuronal cell membrane that are responsible for signal propagation. With sufficient blockage achieved together with calcium, the membrane of the postsynaptic neuron will not depolarize and will thus fail to transmit an action potential. Lidocaine blocks signal conduction in all types of nerves: sensory, motor and autonomic. This block is reversible. Lidocaine is given with adrenaline to

prolong the time of action and systemic absorption, which is very important for well vascularized tissues.
The solution for injection Lidokaine me Adrenaline is used for local anaesthesia by local infiltration.

2. BEFORE YOU TAKE LIDOKAINE ME ADRENALINE

Do not take Lidokaine me Adrenaline if you:

- are hypersensitive to the amide-type local anesthetics or to any of the other ingredients of this medicine;
- suffer from Stokes-Adams syndrome;
- suffer from Wolff-Parkinson-White syndrome;
- suffer from atrioventricular heart block and other cardiac conduction disorders;
- suffer from hypertension; because of adrenaline which has hypertensive effect, it is contraindicated;
- suffer from paroxysmal tachycardia;
- suffer from glaucoma and thyrotoxicose;
- have hypovolemia.

This medicine should not be used to produce anaesthesia in digits of hands and feet, nose, ears or penis.
This medicine should not be injected intravenously.
If you think that any of the above conditions applies to you, talk first to your doctor before using this drug.

Take special care with Lidokaine me Adrenaline

Talk to your doctor if:

- this drug will be used in patients with epilepsy, bradycardia, congestive heart failure, shock, myasthenia gravis, porphyria;
- this drug will be given to elderly or patients with hypertension, cardiac arrhythmias, ischemic heart disease, obstructive cardiomyopathy, phaeochromocytoma, arteriosclerosis, susceptibility to closed-angle glaucoma, prostate disorders, because it contains adrenaline;

- you have severe renal impairment, hepatic and respiratory function impairment (lidocaine is not normally metabolised in the liver, so toxic plasma concentrations can occur);
- you have cardiovascular function impairment, because in this case the ability to adjust functional changes associated with the prolongation of QT interval caused by lidocaine is smaller;
- you suffer from asthma and are sensitive to sulphites, because this drug contains sodium metabisulphite as antioxidant; sulphites can cause allergic reactions to persons sensitive to them;
- the injection is done in an inflamed or infected area, because this can lower the effect of the local anaesthetic and increase the systemic side effects (for this reason it is not advised to use this drug in such areas);
- you suffer from peripheral vascular diseases;
- you suffer from hyperthyroidism or diabetes;
- this drug will be used in patients with glucose-6-phosphate-dehydrogenase insufficiency because it can induce or worsen methemoglobinemia; for this reason it should be used with special caution in patients predisposed to methemoglobinemia or in patients with congenital or idiopathic methemoglobinemia;
- this drug will be used in children because its efficacy and safety is not established in children.

This medicine should only be administered by, or under the supervision of doctors experienced in local anaesthesia and resuscitation techniques. When local anaesthetics are administered parenterally, resuscitation equipment should be available.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, incuding those obtained without a prescription. This is especially important for the following medicines:

- monoamine oxidase inhibitors (IMAO) or tricyclic antidepressants: concomitant use of lidocaine with adrenaline or other local anaesthetics containing adrenaline can cause severe and prolonged hypertension, because IMAOs can potentiate catecholamine effects;
- other antiarrhythmics: lidocaine combined with other antiarrhythmics can potentiate the

cardiac depressant effects;

- cimetidine and beta-blockers can potentiate the effect of lidocaine because they inhibit the liver enzymatic system; there is an increased risk of lidocaine toxicity when given with propranolol; there is an increased risk of severe hypertension and bradycardia when adrenaline is given with non-cardioselective beta-blockers, also response to adrenaline may be reduced;
- barbiturates, benzodiazepines and phenytoin: the use for a long time of these drugs that stimulate the liver enzymatic system can make it necessary to increase the dose of lidocaine;
- acetazolamide, loop diuretics, or thiazide and related diuretics: the effect of lidocaine is antagonized from hypokalaemia caused by these medicines;
- antipsychotics that prolong the QT interval: the risk of ventricular arrhythmias is increased when antiarrhythmics that prolong the QT interval are given with these medicines;
- atazanavir, lopinavir, darunavir and fosamprenavir: plasma concentration of lidocaine is possibly increased by these medicines; avoid concomitant use of lidocaine with fosamprenavir;
- saquinavir: the risk of ventricular arrhythmias is increased when lidocaine is given with this medicine — avoid concomitant use;
- guanethidine: increased risk of hypertension when adrenaline given with guanethidine;
- tolazoline: avoid concomitant use with adrenaline;
- general anaesthetics: increased risk of arrhythmias when adrenaline given with these medicines;
- dopexamine: effects of adrenaline possibly enhanced by dopexamine.

These drugs can be affected by Lidokaine me Adrenaline, or can affect the way it acts. You may need to use different doses of this drug or you may need taking other drugs. Your doctor or pharmacist will advice you.

Pregnancy

Inform your doctor or pharmacist if you are pregnant or think you may be pregnant.
Lidokaine me Adrenaline should not be used in pregnancy, except when the benefit outweighs the risk. Your doctor or pharmacist will discuss on its benefits and risks during pregnancy.

Breastfeeding

Inform your doctor or pharmacist if you are breastfeeding.

The drug should be used with caution in nursing women because lidocaine is excreted in breastmilk. Your doctor or pharmacist will discuss on its benefits and risks if you are breastfeeding or you are planning to do so.

Driving and using machines

Do not use Lidokaine me Adrenaline while driving and using machines because one of its most possible side effects is the one in central nervous system causing dizziness, blurred vision, somnolence etc.

Important information about some of the ingredients of Lidokaine me Adrenaline

This drug contains sodium. To be taken into consideration by patients on a controlled sodium diet.

This drug contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm.

3. HOW TO TAKE LIDOKAINE ME ADRENALINE

This medicine will be administered by a doctor or specialized medical personnel. If you feel that the effects of Lidokaine me Adrenaline are too strong or too weak, please talk to your doctor or pharmacist.

The dose of Lidokaine me Adrenaline depends on the type of anesthesia, the required rate of anesthesia and individual response of the patient. If given in solutions containing adrenaline, the maximum dose of lidocaine is 500 mg. Doses should be reduced in children, in debilitated patients and in the elderly.

This medicine should only be administered by, or under the supervision of doctors experienced in local anaesthesia and resuscitation techniques. When local anaesthetics are administered parenterally, resuscitation equipment should be available.

If you take more Lidokaine me Adrenaline than you should

This medicine will be administered by a doctor or specialised medical personnel, therefore, it is unlikely for an overdose to occur. However, if you think that you have taken a higher dose than you should, then talk to your doctor immediately.

4. POSSIBLE SIDE EFFECTS

All medicines can cause side effects. Sometimes they can be serious, most of the times not. Side effects caused by lidocaine, as well as other local anaesthetics, are rare and usually because of high concentrations in blood, high doses, fast absorption or sometimes because of hypersensitivity, idiosincrasia or low tolerance of the patient.

Do not panic from this list of possible side effects. You may not get any of them.

Talk to your doctor if any of the following side effects bothers you:

- the effects in the nervous system can be of stimulation and / or inhibition nature such as nervousness, anxiety, insomnia, confusion, headache, psychotic state, paraesthesia, tinnitus, muscle twitching, numbness of the tongue and perioral region, dizziness, blurred vision, transient excitation, tremor and then drowsiness, convulsions, loss of consciousness and maybe respiratory failure and coma; the exciting reactions can be very short or may not occur at all;
- cardiovascular effects such as palpitations, tachycardia, angina, hypertension, hypotension, myocardial depression, bradycardia and cardiac arrest also may occur;
- allergic reactions are very rare and are characterized by cutaneous lesions, urticaria, oedema or anaphylactoid reactions;
- reactions located in the skin such as: burning sensation, oedema, itching or redness on the skin in the injection area; these reactions are transient and usually disappear in 1 to 2 hours;
- narrowing of blood vessels and marked whitening in the site of injection can occur or dilatation of blood vessels and redness around injection site;
- other side effects: dyspnoea, weakness, anorexia, nausea, vomiting, pulmonary oedema (particularly in overdosage), tissue necrosis, mydriasis, difficulty in micturition, increased salivation, hypokalaemia, hyperglycaemia.

If you get any other side effect not mentioned in this leaflet, please talk to your doctor or

pharmacist.

5. HOW TO STORE LIDOKAINE ME ADRENALINE

Keep this medicine out of the sight and reach of children.

Do not store above 25°C!

Do not use Lidokaine me Adrenaline after the expiry date which is stated on the packaging.

Keep in the original package to protect it from light.

6. OTHER INFORMATION

What Lidokaine me Adrenaline contains

The **active substances** are lidocaine hydrochloride and adrenaline hydrogentartrate.

Each glass vial 50 ml contains 1000 mg (1 g) lidocaine hydrochloride and 0.5 mg adrenaline (as hydrogentartrate) (2% lidocaine and 0.001% adrenaline (as hydrogentartrate)).

The other ingredients are: sodium metabisulphite, sodium chloride, sodium hydroxide, water for injection.

Contents of the pack

Box with one glass vial of 50 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in December 2023.