PACKAGE LEAFLET: Information for the user

PRODLIDOKAINE / ADRENALINE

Solution for injection

(40 mg + 0.02 mg) / 2 ml

(Lidocaine hydrochloride, Adrenaline hydrogen tartrate)

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 PRODLIDOKAINE / ADRENALINE IS AND WHAT IT IS USED FOR

The solution for injection Prodlidokaine / Adrenaline contains the active substances lidocaine hydrochloride and adrenaline hydrogen tartrate. Lidocaine belongs to the group of local anaesthetics of the amide type. Lidocaine exerts its anaesthetic action by blocking signal generation and conduction in neurons by reducing cell membrane permeability to Na^+ ions. This occurs when lidocaine binds to calcium, and together they bind to Na^+ receptors in the neuronal membrane. As a result, the membrane is stabilised and depolarisation is blocked, which leads to the prevention of action potential and blocking of the signal conduction. Lidocaine blocks signal

generation and 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 Prodlidokaine / Adrenaline is used for local anaesthesia by local infiltration.

2. BEFORE YOU TAKE PRODLIDOKAINE / ADRENALINE

Do not take Prodlidokaine / Adrenaline if you:

- are hypersensitive to the amide – type local anaesthetics 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 a hypertensive effect, it is contraindicated;
- suffer from paroxysmal tachycardia;
- suffer from glaucoma and thyrotoxicosis;
- 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 medicine.

Take special care with Prodlidokaine / Adrenaline

Talk to your doctor if:

- you suffer from epilepsy, bradycardia, congestive heart failure, shock, myasthenia gravis, porphyria;

- you are an elder patient or suffer from poor general condition (hypertension, cardiac arrhythmias, ischemic heart disease, obstructive cardiomyopathy, phaeochromocytoma, arteriosclerosis, susceptibility to closed-angle glaucoma, prostate disorders), because it contains adrenaline;
- you suffer from severe renal impairment, hepatic and respiratory function impairment (lidocaine is not metabolised in liver as usual, so toxic plasma concentrations can occur);
- you suffer from cardiovascular function impairment, because in this case the ability to adjust functional changes associated with the prolongation of QT interval caused by lidocaine is lower;
- you suffer from asthma and are sensitive to sulphites, because this medicine contains sodium metabisulfite as antioxidant; sulphites can cause allergic reactions in persons sensitive to them;
- the solution is injected 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 medicine in such areas);
- you suffer from peripheral vascular diseases;
- you suffer from hyperthyroidism or diabetes;
- you suffer from 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 should be used with caution in children because its efficacy and safety is not yet 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, including those obtained without a prescription. This is especially important for the following medicines:

- monoamine oxidase inhibitors (MAOI): concomitant use of lidocaine with adrenaline or other local anaesthetics containing adrenaline can cause severe and prolonged hypertension, because MAOIs 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 medicines that stimulate the liver enzymatic system can make necessary the increase of lidocaine dose;
- 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 medicines can be affected by Prodlidokaine / Adrenaline, or can affect the way it acts. You may need to use different doses of this medicine or you may need to take other medicines. Your doctor or pharmacist will advise you.

Pregnancy

Inform your doctor or pharmacist if you are pregnant or are planning to get pregnant.
Prodlidokaine / Adrenaline should not be used in pregnancy, except the cases 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.
Lidocaine and adrenaline are excreted in breast milk; however, the amount of lidocaine is too small to be harmful, whereas adrenaline is unlikely to be harmful due to its poor oral bioavailability.
Your doctor or pharmacist will discuss on its benefits and risks during breastfeeding.

Driving and using machines

Driving and using machines should be avoided because one of the most possible side effects of Prodlidokaine / Adrenaline is the effect on the central nervous system causing dizziness, blurred vision, somnolence, etc.

Important information about some of the ingredients of Prodlidokaine / Adrenaline

This medicine contains sodium. To be taken into consideration by patients on a controlled sodium diet.
This medicine contains sodium metabisulfite which may rarely cause severe hypersensitivity reactions and bronchospasm.

3. HOW TO TAKE PRODLIDOKAINE / ADRENALINE

This medicine will be administered by doctor or specialised medical personnel. If you feel that the effects of Prodlidokaine / Adrenaline are too strong or too weak, talk to your doctor or pharmacist.

The dose of Prodlidokaine / Adrenaline depends on the type of anaesthesia, the required rate of anaesthesia and individual response of the patient. In general, the doses should be reduced in children, debilitated patients, and the elderly.

This medicine contains lidocaine, which 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 feel that the effects of Prodlidokaine / Adrenaline are too strong or too weak, please talk to your doctor or pharmacist.

If you take more Prodlidokaine / Adrenaline than you should

This medicine will be administered by 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 happen because of high concentrations in blood, high doses, fast absorption or sometimes because of hypersensitivity, idiosyncrasy 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 central 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 excitatory reactions can be very short or may not

occur at all;

- cardiovascular effects may be: palpitations, tachycardia, angina, hypertension, hypotension, myocardial depression, bradycardia and cardiac arrest may also 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 of 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 or dilatation of blood vessels and redness around injection site may occur;
- other side effects: dyspnoea, weakness, anorexia, nausea, vomiting, pulmonary oedema (particularly in overdosage), tissue necrosis, mydriasis, difficulty in micturition, increased salivation, hypokalaemia, hypoglycaemia, neuropathy, peripheral nerve injury, diplopia.

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

5. HOW TO STORE PRODLIDOKAINE / ADRENALINE

Keep out of the sight and reach of children!
Store below 25°C!
Do not use Prodlidokaine / Adrenaline after the expiry date which is stated on the packaging.
Keep in the original package to protect from light.

6. OTHER INFORMATION

What Prodlidokaine / Adrenaline contains

The active substances are lidocaine hydrochloride and adrenaline hydrogen tartrate.
Each ampoule 2 ml contains 40 mg lidocaine hydrochloride and 0.02 mg adrenaline (as hydrogen tartrate) (2% lidocaine hydrochloride and 0.001% adrenaline (as hydrogen tartrate)).
The other ingredients are: sodium metabisulphite, sodium chloride, sodium hydroxide, water for injection.

Content of the pack

Box with 10 ampoules of 2 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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