MercuryPharma

Package leaflet: Information for the patient

Lidocaine Hydrochloride 0.5% w/v Solution for Injection
Lidocaine Hydrochloride 1% w/v Solution for Injection
Lidocaine Hydrochloride 2% w/v Solution for Injection

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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 you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leafleat. See section 4.

The product is referred as above but for ease it has been mentioned as Lidocaine hydrochloride throughout the leaflet.

What is in this leaflet

1. WHAT LIDOCAINE HYDROCHLORIDE IS AND WHAT IT IS USED FOR

Lidocaine Hydrochloride is a local anaesthetic and belongs to a class of drugs called amide type local anaesthetics. It produces loss of feeling or sensation confined to one part of the body.

Lidocaine Hydrochloride Injection may be used to produce local numbness (anaesthesia) by injection of the solution into or around the area of operation. It may also be used to produce local anaesthesia by injection of the solution close to the nerves whose conduction is to be cut off, or into the epidural space near the spinal cord, or by administering the solution into a vein in a limb that has been isolated from the circulation by means of a tourniquet (bandage that stops the flow of blood from vessel by applying pressure).

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN LIDOCAINE HYDROCHLORIDE

You should not be given this medicine:
- if you know you are allergic to lidocaine hydrochloride, to any of the other ingredients of this medicine (listed in section 6) or to other similar amide type anaesthetics
- if you suffer from state of decreased blood volume (hypovolaemia)
- if you suffer from abnormality of impulse propagation in the heart causing decreased blood pressure, slow heart rate (complete heart block)
- If the solution also contains adrenaline, lidocaine hydrochloride should not be injected into a vein or used in areas such as fingers, toes, ears, nose or penis, as the blood supply to these areas might become inadequate

Speak to your doctor if one of these applies to you *before* you are given this medicine.

Warnings and precautions

Talk to your doctor or nurse before you are given Lidocaine Hydrochloride if:
- you suffer from any heart problem, particularly if it affects the heart rate
- you suffer from fits (epilepsy)
- you have low concentration of potassium in the blood causing muscle cramps, constipation (hypokalaemia)
- you ever had an allergic reaction to local anaesthetic e.g. a skin rash or breathlessness or collapse
- you have had recent vomiting, diarrhoea or bleeding, or if you have not been drinking normal amounts of fluid
- you are feeling ill and run down
- you have been told that you have too much acid in your blood and tissues, or not enough oxygen
- you suffer from any liver disease or kidney problems
- you have porphyria (a rare inherited disease that affects the skin and nervous system)
- you have an infection of the skin with pus at or near the site to be injected
- you have problems with your breathing
- you are pregnant, likely to become pregnant or breast-feeding
- you suffer from loss of muscle function and weakness (myasthenia gravis).

Use in children

Lidocaine injection is not recommended for use in neonates (less than a month old).

Other medicines and Lidocaine Hydrochloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

A large number of drugs can interact with Lidocaine Hydrochloride which can significantly alter their effects. These drugs include:
- medicines used to treat high blood pressure such as diuretics (water tablets) betablockers, e.g. timolol and propranolol and calcium channel blockers, e.g. verapamil, prenylamine
- medicines used in the treatment of stomach ulcers (e.g. ranitidine, cimetidine)
- dopamine used to stimulate the heart and to treat shock
- strong pain relieving medicines such as codeine and pethidine (Narcotics or opioid drugs)
- medicines used to treat certain types of muscle jerking (e.g. Serotonin or 5-hydroxytryptamine)
- medicines used to treat viral infection (e.g. amprenavir, atazanavir, darunavir and lopinavir)
- medicines used to treat irregular heart beat (mexiletine, amiodarone)
- medicines used to treat infections (quinupristin/dalfopristin)
- medicines used to treat mental disorders (pimozide, sertindole, olanzapine, quetiapine, zotepine)
- medicines used to treat nausea and vomiting (tropisetron, dolasetron).

If adrenaline (epinephrine) is to be added to your lidocaine injection, you should also tell your doctor if you suffer from high blood pressure, shortage of blood supply to the brain, an overactive thyroid gland or if you are taking antidepressant drugs.

If you are already taking one of these medicines, speak to your doctor before you receive Lidocaine Hydrochloride.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Lidocaine Hydrochloride should only be used during pregnancy and breast feeding if absolutely necessary.

continued overleaf

PATIENT INFORMATION LEAFLET

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Lidocaine Hydrochloride 1% w/v Solution for Injection

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Driving and using machines:
Certain areas of your body will be numb for about 2-4 hours after having this medicine. If this is likely to affect your ability to drive or use machinery you should wait for the effect to wear off.

In general, it is wise to ask your doctor whether it is safe to drive.

Lidocaine Hydrochloride contain sodium
This medicinal product contains less than 1mmol sodium (23mg) per dose, i.e. essentially 'sodium-free'.

3. HOW LIDOCAINE HYDROCHLORIDE IS GIVEN TO YOU

The site of injection will depend on the area to be numbed. It will be administered by a trained healthcare professional. The maximum dose for a healthy adult is 200mg. Your doctor will decide the most suitable dosage for your particular case according to your age and physical circumstances as well as the site of injection, the method used and your response to the injection. If you have any concerns or questions about how much of this medicine you have received, speak to your doctor immediately.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lidocaine Hydrochloride can cause side effects, although not everyone gets them.

All medicines can cause allergic reactions although serious allergic reactions are rare.

Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately. Lidocaine may result in abnormal amount of methemoglobin (a form of hemoglobin in blood) which may cause bluish discoloration of skin, headache, shortness of breath, malaise and fatigue.

Other serious side effects are also rare, but may occur if too much Lidocaine Hydrochloride is given or if the drug is unintentionally injected into a blood vessel.

Such side effects may occur with certain frequency, which is defined as follows:

Not known: frequency cannot be estimated from the available data

- changes in the rhythm and speed of the heart
- low blood pressure
- slow heart rate (less than 60 beats/minute)
- cessation of normal circulation of blood due to failure of the heart
- pain at the injection site, or numbness or loss of power after the effects of the injection should have worn off
- temporary pain sensation at the lower back, buttocks, legs which resolves within a few days
- numbness or tingling/paralysis of legs after administration of lidocaine in the spine
- difficulty in passing water, problems with the frequency, consistency and/or ability to control your bowel movements (bowel dysfunction)
- loss of balance, pins and needles around the mouth, numbness of the tongue, difficulty tolerating everyday sounds (hyperacusis), ringing in the ears (tinnitus), dizziness or lightheadedness, confusion, nervousness, restless or twitching, changes in your normal mood or behaviour, involuntary rhythmic muscular contractions, fits or seizures, profound state of unconsciousness (coma)
- allergic reaction to local anaesthetic e.g. a skin rash or breathlessness or collapse
- feelings of anxiety or fear
- blurred vision, double vision or transient visual loss
- feeling sick (nausea) or being sick (vomiting)
- breathlessness
- cessation of breathing (respiratory arrest)
- feeling drowsy or faint.

Note : If you are having a blood test, tell your doctor, as injection of lidocaine into a muscle can increase the blood levels of an enzyme marker for muscle damage.
If any of the side effects become serious, or if you notice any 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LIDOCAINE HYDROCHLORIDE

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

Do not use this medicine after the expiry date which is stated on the carton and ampoule label after 'Exp'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the container in the outer carton in order to protect from light.

The solution should not be used if it is discoloured in any way.

This medicine should not be mixed with any other drugs.

If only part of an ampoule is used, the remaining solution should be discarded.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lidocaine Hydrochloride Contains
The active substance is lidocaine hydrochloride.

Lidocaine Hydrochloride Injection BP 0.5% w/v, each 1ml of which contains 5mg of active ingredient.

Lidocaine Hydrochloride Injection BP 1% w/v, each 1ml of which contains 10mg of active ingredient.

Lidocaine Hydrochloride Injection BP 2% w/v, each 1ml of which contains 20mg of active ingredient.

The other ingredients are sodium chloride, sodium hydroxide or hydrochloric acid and water for injections.

What Lidocaine Hydrochloride looks like and contents of the pack
Lidocaine Hydrochloride is a clear colourless, sterile solution for injection.

Lidocaine Hydrochloride Injection BP 0.5% w/v is available in 10ml clear glass ampoules, packed in boxes of 10 ampoules.

Lidocaine Hydrochloride Injection BP 1% w/v is available in 2ml, 5ml, 10ml and 20ml clear glass ampoules, packed in boxes of 10 ampoules.

Lidocaine Hydrochloride Injection BP 2% w/v is available in 2ml, 5ml, 10ml and 20ml clear glass ampoules, packed in boxes of 10 ampoules.

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