Package leaflet: Information for the patient

Lidocaine 10 mg/ml (1 % w/v) solution for injection in pre-filled syringe
Lidocaine hydrochloride

Read all of this leaflet carefully before you are given 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lidocaine is and what it is used for

Lidocaine contains the active substance lidocaine hydrochloride.
Lidocaine is a local anaesthetic. It is used to numb parts of the body during surgical procedures. It stops the nerves from being able to pass pain messages to the brain and so stops you feeling pain.

2. What you need to know before you are given Lidocaine

You must not be given Lidocaine :
- if you are allergic to lidocaine, local anaesthetics of the amide type or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Lidocaine :
- if you suffer from epilepsy. Your doctor will monitor you closely for manifestation of symptoms.
- if you have kidney or liver disease.
- if you have a disease leading to muscle weakness (myasthenia gravis).
- if you have heart disorders including conduction disorders, slow heartbeat.
- if you have respiratory depression (breathing difficulties with slow and shallow breathing).
- if you are elderly or have a poor general health condition.
- if you have, or are treated for, bleeding disorders.

Additionally your doctor knows that an injection of this medicine into inflamed tissue may lead to an increased uptake of the active substance into the circulation and the effect of the active substance on your body will be weakened.

Your doctor will consider that there is an increased risk of side effects on the nervous system if this medicine is administered in the head and neck region.

Children and adolescents

Lidocaine 10 mg/ml (1 % w/v) should not be used for children below 2 years of age.

Other medicines and Lidocaine
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Lidocaine may affect or be affected by other medicines.

In particular, tell your doctor if you are taking any of the following:
- medicines used to treat high blood pressure such as diuretics (water tablets);
- medicines used to treat heart disorders including irregular heartbeats, such as beta blockers (e.g. metoprolol, propranolol) or calcium channel blockers (e.g. amiodarone);
- medicines that narrow your blood vessels (vasoconstrictors, e.g. epinephrine, norephinephrine);
- medicines used to relax muscles during general anaesthesia (e.g. suxamethonium);
- sleeping pills and medicines that reduce your level of consciousness (sedatives);
- medicines that increase the risk of getting fits and seizures (e.g. tramadol, bupropion);
- medicines that decrease the risk of getting fits and seizures (e.g. diazepam);
- cimetidine, a medicine used to treat heartburn;
- antivirals medicines (e.g. ritonavir), macrolides antibiotics (e.g. erythromycine) or antifungals (e.g. ketoconazole, itraconazole);
- ciprofloxacin (antibiotics);
- medicines used to treat epilepsy (phenobarbital, phenytoin, carbamazepine or primidone);
- fluvoxamine, a medicine used in the treatment of mental illness;
- medicines used to reduce pressure within the eye (e.g. acetazolamide);
- other anaesthetics, including local anaesthetics.

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 or pharmacist for advice before you are given this medicine. Then your doctor will decide if you should be given this medicine.

Pregnancy
Your doctor will only administer this medicine while you are pregnant if he/ she considers it as necessary. The dose should be as low as possible.

Breast-feeding
Lidocaine passes into human breastmilk in small amounts. The use of lidocaine at recommended doses is unlikely to affect the breast-fed child. Breast-feeding can therefore be continued during use of lidocaine.

Driving and using machines
Lidocaine may affect your ability to drive or operate machines. Ask your doctor about when it would be safe to drive or operate machines.

Lidocaine contains sodium

This medicine contains 32 mg sodium (main component of cooking/table salt) in each syringe. This is equivalent to 1.6 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How Lidocaine is given

The administration will be performed by a healthcare professional with appropriate training and relevant experience.

Your doctor will decide the most suitable dosage for your particular case according to your age and medical condition as well as for the site of injection, the method used and your response to the injection.

Use in children and adolescents
Lidocaine 10 mg/ml (1 % w/v) should not be used for children below 2 years of age.

Method of administration
Lidocaine will be given to you as an infiltration (intradermal, subcutaneous, or submucosal use) injection into the surroundings of peripheral nerves.

If you are given more Lidocaine than you should
Since this medicine is administered to you by a trained healthcare professional, it is unlikely that you will be given too much of Lidocaine .

Whether you develop symptoms of an overdose or not depends on the level of this medicine present in your blood. The more lidocaine is in your blood and the more rapidly it is given to you, the more frequently and severely you might experience symptoms of an overdosage.

A small overdose mainly affects your central nervous system. Side effects that do occur will disappear in most cases after stopping lidocaine administration.

Nevertheless, if you think you have been given too much medicine, or you begin to experience dizziness or lightheadness, numbness of the tongue, a ringing in the ear, vomiting or shivering, you must tell the person giving you the injection immediately. Your doctor will know how to manage these symptoms and give you any necessary treatment.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects may be serious. Seek immediately medical help if you have an allergic reaction causing:
- swelling of the hands, feet, face, lips, mouth, tongue or throat
- difficulties in breathing
- itchy skin rash
- fever
- drop in blood pressure and shock

These side effects are rare (may affect up to 1 in 1,000 people).

Other side effects may include:

<u>Very common (may affect more than 1 in 10 people)</u>
- nausea

<u>Common (may affect up to 1 in 10 people)</u>
- sensation of tickling, tingling, burning, pricking, or numbness (paresthesia)
- loss of consciousness,
- pain or shivering due to injections
- slow heartbeat
- low blood pressure or high blood pressure
- vomiting

Rare (may affect up to 1 in 1,000 people)
- changes in sensations or muscle weakness (neuropathy)
- convulsions (seizures)
- partial paralysis
- headache accompanied by a ringing or clicking sound in your ears (tinnitus) and an abnormal intolerance to light (photophobia)
- hearing loss (deafness)
- damages of your brain nerves
- drop of your eyelid(s) combined with the narrowing of your pupils and sometimes decreased sweating (Horner's syndrome). It occurs after application in the head/neck region
- asymmetric sweating and flushing of the upper chest, neck or face (Harlequin syndrome)
- irregular heartbeats
- cardiac arrest
- double vision
- slowed or stopped breathing
- skin rash or hives

Frequency Not known (cannot be estimated based on available data)
- bluish discoloration of the skin, headaches, shortness of breath and tiredness due to abnormal quantities of methaemoglobin (a form of haemoglobin which has a reduced capacity to bind oxygen) in the blood (methaemoglobinaemia)

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
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lidocaine

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

You should not be given this medicine after the expiry date which is stated on the syringe label, blister and carton. The expiry date refers to the last day of that month.

Keep the pre-filled syringe in its unopened blister until use. Do not freeze.
After opening, the medicine must be used immediately.

This medicine must not be used if there are visible signs of deterioration.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lidocaine contains
The active substance is Lidocaine hydrochloride.
- Each ml of solution for injection contains 10 mg of lidocaine hydrochloride (as lidocaine hydrochloride monohydrate).
- Each 10 ml pre-filled syringe contains 100 mg of lidocaine hydrochloride (as lidocaine hydrochloride monohydrate).

The other ingredients are: sodium chloride, sodium hydroxide, hydrochloric acid, concentrated (for pH adjustment), water for injections.

What Lidocaine looks like and contents of the pack
Lidocaine is a clear colourless solution for injection (injection). Lidocaine is available in a 10 ml polypropylene pre-filled syringe, individually packaged in a transparent blister pack. Cardboard box of 1 or 10 pre-filled syringes. Not all pack sizes may be marketed.

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The following information is intended for healthcare professionals only:

Please prepare the pre-filled syringe carefully as follows

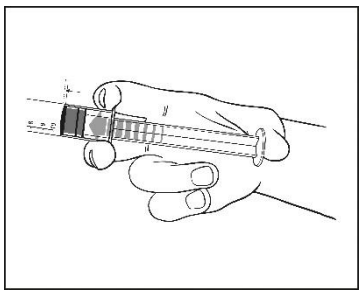
The pre-filled syringe is for single patient use only. Discard the pre-filled syringe after use. Do not reuse.

The content of un-opened and un-damaged blister is sterile, and must not be opened until use.
The medicine should be inspected visually for particles and discoloration prior to administration. Only clear colourless solution free from particles or precipitates should be used.
The medicine should not be used if the tamper evident seal on the syringe is broken.

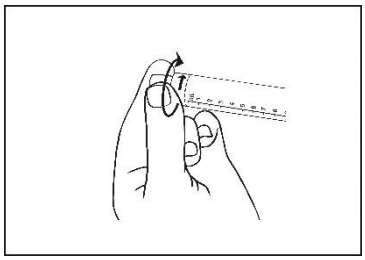
The external surface of the pre-filled syringe is sterile until blister is opened.

When handled using an aseptic method, this medicine can be placed on a sterile field.

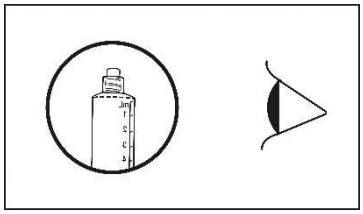
1) Withdraw the pre-filled syringe from the sterile blister.



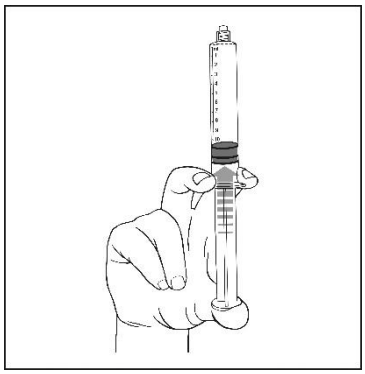
2) Push on the plunger to free the bung. The sterilisation process may have caused adhesion of the bung to the body of the pre-filled syringe.



3) Twist off the end cap to break the seal. Do not touch the exposed luer connection in order to avoid contamination.



4) Check the pre-filled syringe seal tip has been completely removed. If not, replace the cap and twist again



5) Expel the air by gently pushing the plunger.

6) Connect the pre-filled syringe to access device or the needle. Push the plunger slowly to inject the required volume.