
 advertising & communication services Ltd.	Artwork No.	-		Colours Used
	Customer	Accord		Pantone Black
	Description	Lidocaine 1%, 2% w/v solution (Lidocaine Hydrochloride)		
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	Language	English		
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	Version No.	10 (Page 1 of 2) (01-15-piq)		
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Prepared By Regulatory Affairs		Checked By Regulatory Affairs		Approved By Quality Assurance



Package leaflet: Information for the user
Lidocaine 1% w/v, 2% w/v solution for injection
(Lidocaine Hydrochloride)



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 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

The product is referred as above but for ease it has been mentioned as Lidocaine solution for injection through the leaflet.

What is in this leaflet:

1. What Lidocaine solution for injection is and what it is used for
2. What you need to know before you use Lidocaine solution for injection
3. How to use Lidocaine solution for injection
4. Possible side effects
5. How to store Lidocaine solution for injection
6. Contents of the pack and other information

1. What Lidocaine solution for injection is and what it is used for

Lidocaine Hydrochloride is a local anesthetic and belongs to a class of drugs called amide type local anesthetics. It produces loss of feeling or sensation confined to one part of the body. Lidocaine Hydrochloride Injection may be used to produce local numbness (anesthesia) by injection of the solution into or around the area of operation. It may also be used to produce local anesthesia 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 use Lidocaine solution for injection

You should not be given this medicine:

- if you are allergic to lidocaine hydrochloride, to any of the other ingredients of this medicine (listed in section 6 of this leaflet)
- if you are allergic 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 pharmacist before using Lidocaine solution for injection

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

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

Other medicines and Lidocaine solution for injection

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

In particular tell your doctor if you are taking:

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 solution for injection, you should 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 about to receive a strong anesthetic to put you to sleep, you should tell your doctor if you have already received an injection of lidocaine containing adrenaline (epinephrine).

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 taking any medicine. Lidocaine solution for injection should only be used during pregnancy and breast feeding if absolutely necessary.

Lidocaine solution for injection Lidocaine may get into breast milk. If you are breast-feeding you should discuss options with your doctor.

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. Ask your doctor when it would be safe to resume these activities.



Lidocaine solution for injection contains Sodium

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

3. How to use Lidocaine solution for injection

Lidocaine solution for injection may be used to produce local anaesthesia by injection of the solution into or around a peripheral nerve or network of nerves. It may also be used to relieve pain by administering the solution into the epidural space, which is close to the spinal cord, or into a vein in a limb that has been isolated from the circulation by means of a tourniquet. If you are unsure why you have been given this product and how to use it, ask your doctor to explain. Your doctor will decide what dose is right for you. The maximum dose for healthy adults should not exceed 200 mg. The dose will depend on your size, your state of health, the part of the body that the medicine is injected into and what the medicine is being used for. For most procedures, one dose is enough but more doses may be needed if the procedure takes a long time.



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If you use more Lidocaine solution for injection than you should

If you think you have been given too much of this medicine, tell your doctor.

If you miss a dose of Lidocaine solution for injection

If you think you have missed a dose of this medicine, tell your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody 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 reactions may include:

- 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 heart attack.
- pain at the injection site, or numbness or weakness of the muscle of the lower legs 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 behavior, 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 temporary loss of vision
- feeling sick (nausea) or sick (vomiting)
- difficulty in breathing
- decreased rate of breathing or breathing may stop
- 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.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

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

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

5. How to store Lidocaine solution for injection

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

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the ampoule/vial and carton.

The expiry date refers to the last day of that month.

For single use only.

Discard any unused contents.

The product should be used immediately after opening.

Do not use this medicine if you notice the contents are discoloured in any way. The injection should not be used if there are particles present.

Do not throw away any medicines via wastewater or household waste. 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 solution for injection contains

The active substance is lidocaine hydrochloride.

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

What Lidocaine solution for injection looks like and the contents of the pack

Lidocaine solution for injection is a clear, colourless, sterile solution for injection. It is available in two strengths, 1% w/v and 2% w/v.

Lidocaine 1% w/v solution for injection:

Each 1 ml of solution contains 10 mg of lidocaine hydrochloride.

Lidocaine 1% w/v solution for injection is available in 2 ml glass ampoules packed in cartons of 5, 10 and 20 ampoules, 5 ml and 10 ml glass ampoules packed in cartons of 10 and 20 ampoules 20 ml, 50 ml and 100 ml glass vial with rubber stopper and aluminium flip-off seal packed in mono carton.

Lidocaine 2% w/v solution for injection:

Each 1 ml of solution contains 20 mg of lidocaine hydrochloride.

Lidocaine 2% w/v solution for injection is available in 2ml, 5 ml and 10 ml glass ampoules packed in cartons of 10 and 20 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Accord Healthcare Limited,

Sage House, 319 Pinner Road, North Harrow, Middlesex HA1 4HF, United Kingdom

For any further information about this medicinal product, please contact the Marketing Authorisation Holder.

This leaflet was last revised in 10/2015.