

PACKAGE LEAFLET: INFORMATION FOR THE USER

B. Braun Melsungen AG · 34209 Melsungen, Germany

2% w/v Lidocaine Injection
solution for injection

Lidocaine hydrochloride monohydrate

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 or nurse.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What 2% w/v Lidocaine Injection is and what it is used for

2% w/v Lidocaine Injection contains the active substance lidocaine hydrochloride. Lidocaine is a locally and regionally acting anaesthetic. It is used to numb a defined body area before a surgical operation in adults and children. However, if your doctor intends to give this medicine to a child special precautions apply (see also 'How to use 2% w/v Lidocaine Injection'). It is of special note that there are only limited data available on the use of this medicine in children under 2 years. Additionally it may be used to control a severe fast or abnormal heart beat (ventricular tachycardia or tachyarrhythmia). But only if your doctor has assessed your condition as life threatening. For these purposes this medicine may be given to adults and children. However if your doctor intends to give this medicine to a child special precautions apply (see also 'How to use 2% w/v Lidocaine Injection'). It is of special note that there are only limited data available on the use of this medicine in children.

2. What you need to know before you use 2% w/v Lidocaine Injection

You must not be given 2% w/v Lidocaine Injection

- if you are allergic to lidocaine or similar substances that are also used as local anaesthetics or any of the other ingredients of this medicine (listed in section 6)
- It must not be used for *special techniques in the field of local and regional anaesthesia called epidural or spinal anaesthesia*¹ if you have
 - uncorrected blood volume deficit (hypovolemia)
 - compromised blood clotting function (coagulopathy)
 - increased pressure within the skull
 - bleeding within the skull or within the spine.
- It must not be used for *control of fast or abnormal heart beat* if
 - you have severe heart disorders in particular when your heart beats irregularly, or beats slowly,
 - you experienced a heart attack within the last 3 months or if the ability of your heart to pump blood throughout your body is markedly decreased unless your condition is life-threatening.

¹Epidural or spinal anaesthesia means application of the anaesthetic to the spinal cord.

Warnings and precautions

Before this medicine is given to you, your doctor will make sure that all equipment for the treatment of emergencies and for resuscitation is available.

Under certain conditions you may receive this medicine only under close medical supervision. Your doctor will take particular caution if you have any of the following conditions:

- previous allergy to local anaesthetics
- problems with your heart or your lungs
- diseases of the liver and kidneys
- a special severe muscle weakness (Myasthenia gravis)
- severe shock
- any condition that may lead to an increased risk of fits and seizures (epilepsy)

Local and regional anaesthesia

- Your doctor will take into account that especially when you are an elderly patient you may experience low blood pressure as a complication of spinal and epidural anaesthesia¹.
- Additionally your doctor knows that an injection of this medicine into inflamed tissue may lead to an increased uptake of the drug into the circulation and the effect of the drug on your body will be weakened.
- If you are below the age of 30 there might be a risk of headache after spinal anaesthesia. Your doctor will use a small needle to reduce this risk.
- Additionally there is a risk of increased side effects when the tourniquet is removed after injection into a vein. Therefore your doctor will drain off this medicine in several portions.
- Your doctor will consider that there is an increased risk of side effects on the nervous system if this medicine is given to your head and neck region.

Control of fast or abnormal heart beat

- Your doctor will administer this medicine for the treatment of heart problems only with special caution if you have high blood acidity (acidosis).
 - If you receive this medicine your
 - electrocardiogram,
 - blood pressure,
 - state of consciousness and
 - breathing will be supervised.
- If one of the named parameters is getting worse your doctor may need to revise your therapy. Additionally it will be made sure that during therapy that usual equipment for emergencies is available.
- If you receive this medicine over a longer period of time your doctor will assure that
 - your fluid balance,
 - blood salt levels and
 - your acid-base balance will be monitored.
 - If you receive large amounts of this medicine your doctor will correct
 - any existing low potassium levels in your blood,
 - a deficit of oxygen and
 - disorders of your acid-base balance before start of infusion/injection.

Note:

If you are under anaesthesia your doctor will examine your condition very carefully. This will be done because side effects affecting your nervous system and your heart may remain unrecognised and can occur without previous warning symptoms.

Other medicines and 2% w/v Lidocaine Injection

Tell your doctor or pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This is necessary as your doctor has to check if the medicines you are taking are metabolized via special enzymes in the body or are influencing their function (Cytochromes P450 1A2 and 3A4). This is done to avoid interactions between 2% w/v Lidocaine Injection and other medicines you are taking.

In particular, your doctor will have to know if you are taking any of the following:

- some heart medicines, namely special beta blockers (e.g. metoprolol, propranolol) or so-called calcium channel blockers (e.g. amiodarone)
- antiarrhythmics – medicines for the treatment of irregular heart beat
- medicines that narrow your blood vessels (vasoconstrictors,e.g. epinephrine, norepinephrine)
- cimetidine, a medicine used to treat heartburn
- antivirals – medicines for the treatment of HIV
- sleeping pills and medicines that reduce your level of consciousness (sedatives) or cause drowsiness
- phenytoin, carbamazepine or primidone that are medicines for the treatment of epilepsy
- phenobarbital, which is used in general anaesthesia to make you sleep
- medicines that increase the risk of getting fits and seizures (e.g. tramadol, bupropion)
- the antibiotic erythromycin,
- anti-psychotics (fluvoxamine), which are used in the treatment of mental illness
- medicines used to relax muscles in general anaesthesia
- other anaesthetics.

Pregnancy and breast-feeding and fertility

Please tell your doctor if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. 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 or its metabolites are secreted in small amounts into breast milk. Your doctor will therefore be particularly careful if you are breast feeding. In general, however, at normal doses of this medicine this will not have an effect on your breastfed newborn/infant. So you will not have to discontinue breast-feeding.

Driving and using machines

This medicine may affect your ability to drive or operate machinery depending on where and how it is given to you. Please ask your doctor, especially if areas of your body involved in driving or operating machinery have been under anaesthesia. If your doctor considers it as necessary you should not drive or operate machinery.

2% w/v Lidocaine Injection contains sodium

2 ml, 5 ml and 10 ml ampoule:

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.

20 ml ampoule:

This medicine contains 43.7 mg sodium (main component of cooking/table salt) in each ampoule. This is equivalent to 2.2 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use 2% w/v Lidocaine Injection

This medicine is administered to you by a doctor.

You will receive this medicine as an injection into either a vein, the skin, muscle, bone, spine or nerve area.

Dosage

Your doctor will decide how much medicine you will receive. This depends on your individual situation.

Use in special patient groups

In certain groups of people the dose of lidocaine given may need to be reduced depending on for which purpose this medicine is given to you. This includes:

- pregnant women
- babies
- young children
- children with high body weight
- the elderly
- people who have a general poor condition
- people with reduced protein binding capacity
- people with kidney impairment
- people with heart and/or liver disease.

Local and regional anaesthesia

Use in adults

The normal maximum dosage is 4.5 mg/kg body weight (or 300 mg). If combined with a suitable medicine that narrows your blood vessels the maximum dosage may be increased up to 7 mg/kg body weight (or 500 mg).

Use in children and adolescents

The dose of your child will be calculated individually according to the age, body weight and the nature of the procedure. The maximum dosage for children is 5 mg/kg body weight. If combined with a suitable medicine that narrows your blood vessels the maximum dosage may be increased up to 7 mg/kg body weight. For anaesthesia in children only a low strength of this medicine (0.5%) should be used.

This medicine has to be used with caution in children younger than 2 years.

Control of fast or abnormal heart beat

The dosage must be adjusted according to individual requirements and the therapeutic effect. This especially applies when you are suffering from problems with your heart, liver or kidneys or during pregnancy.

If you received more 2% w/v Lidocaine Injection than you should

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. Adverse effects that do occur will disappear in most cases after stopping lidocaine administration.

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Symptoms appearing mainly at the beginning of lidocaine poisoning include:

- unpleasant sensations around the mouth
- feeling of tingling, pricking, or numbness (paraesthesia)
- unrest, sleepiness, dizziness
- slurred speech, blurred vision
- disturbance of vision and hearing, tinnitus
- muscle twitching, seizures
- flushing
- high blood pressure
- fast heartbeat
- vomiting, feeling sick
- hallucination, euphoria, anxiety
- shivering

The more serious symptoms include

- sudden drop of blood pressure
- paleness of skin
- impairment or even loss of consciousness (coma)
- stop of breathing
- disappearance of pulse
- heart attack, slow heart beat or irregular heart beat
- death.

If such severe symptoms appear, your doctor will know how to manage these and give you any necessary treatment.

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

4. Possible side effects

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

The frequency and severity of the side effects of this medicine depend upon the dose, how it is given to you and your individual response to lidocaine.

Symptoms of local poisoning may occur after you were given this medicine. Side effects related to your whole body may occur at concentrations of lidocaine in the blood exceeding 5-10 mg/l. You might experience symptoms affecting your central nervous system, your circulation and your heart (see also section 'If you received more 2% w/v Lidocaine Injection than you should').

Depending on the way you were given this medicine side effects affecting your whole body are more frequently associated when given to you for the control of fast or abnormal heart beat.

Local and regional anaesthesia

The following side effects may be serious. If any of the following side effects occur, please tell your doctor immediately. Immediate treatment might be needed:

Rare (may affect up to 1 in 1 000 people):

- allergic reactions ranging from rashes and swelling to severe allergic reactions such as drop of blood pressure, difficulty breathing, constriction of airways and shock
- compression of the spinal cord due to the development of bruise
- partial or complete paralysis
- numbness or paralysis in limbs that do not resolve
- *Cauda equina syndrome*: compression of a special kind of nerve roots manifesting in the form of weakness of the muscles of the lower extremities, loss of control over passing stools and urine and loss of sensation in the area of the buttocks
- lesions of your brain nerves.

Not known (frequency cannot be estimated from the available data):

- methaemoglobinaemia: a disorder leading to a reduction of the oxygen level in the blood, the skin takes on a blue color

Other side effects include

Very common (may affect more than 1 in 10 people):

- feeling sick, vomiting

Common (may affect up to 1 in 10 people)

- pain in legs and lower back after epidural or spinal anaesthesia. The pain may last up to 5 days and will resolve without further treatment.

Rare (may affect up to 1 in 1 000 people):

- sensation of tickling, tingling, burning, pricking or numbness
- headaches accompanied by sensitivity to sunlight (photophobia) and hearing (tinnitus)
- shivering, deafness, or trauma
- transient irritation of the nerve roots due to spinal anaesthesia.

Not known (frequency cannot be estimated from the available data):

- an affection of eyelids, eye muscles and iris, called Horner's syndrome. It occurs after epidural anaesthesia or application in the head/neck region

Control of fast or abnormal heart beat

The following side effects may be serious. If any of the following side effects occur, please tell your doctor immediately. Immediate treatment might be needed:

Rare (may affect up to 1 in 1 000 people):

- allergic reactions ranging from rashes and swelling to severe allergic reactions such as drop of blood pressure, difficulty breathing, constriction of airways and shock
- muscular twitching up to generalized fits and seizures
- depressed level of consciousness up to coma
- slow heart beat, heart block up to heart arrest
- low blood pressure
- difficulties in breathing up to stop of breathing

Very rare (may affect up to 1 in 10 000 people):

- fast heart beat

Other side effects include:

Very common (may affect more than 1 in 10 people):

- feeling sick, vomiting
- anxiety, difficulties in swallowing

Common (may affect up to 1 in 10 people):

- confusion, restlessness, irritability, euphoria, hallucinations, depression
- sleepiness, dizziness, feeling of spinning, slurred speech, tinnitus, blurred vision
- sensation of tickling, tingling, burning, pricking, or numbness of the skin

Elderly patients

Elderly patients may be more prone to some of the effects mentioned above.

Children

Frequency, type and severity of side effects in children are expected to be the same as in adults.

Reporting of side effects

If you get any side effects, talk to your doctor or 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, Website:www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store 2% w/v Lidocaine 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 and the outer carton after "EXP".

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

Containers are for single use only. Unused contents of containers once opened must be discarded.

Solution is to be administered immediately after opening the container.

The solution is only to be used if the solution is clear and colourless and the container and its closure are undamaged.

6. Contents of the pack and other information

What 2% w/v Lidocaine Injection contains

- The active substance is lidocaine hydrochloride monohydrate.
 - One ml of the solution for injection contains 20 mg of lidocaine hydrochloride monohydrate.
 - One ampoule of 2 ml contains 40 mg of lidocaine hydrochloride monohydrate.
 - One ampoule of 5 ml contains 100 mg of lidocaine hydrochloride monohydrate.
 - One ampoule of 10 ml contains 200 mg of lidocaine hydrochloride monohydrate.
 - One ampoule of 20 ml contains 400 mg of lidocaine hydrochloride monohydrate.
- The other ingredients are sodium chloride, sodium hydroxide and water for injections.

What 2% w/v Lidocaine Injection looks like and contents of the pack

2% w/v Lidocaine Injection is a solution for injection.

It is a clear colourless solution of the aforementioned ingredients in water.

It comes in polyethylene plastic ampoules holding 2 ml, 5 ml, 10 ml or 20 ml.

It is supplied in packs of 20 ampoules of each size or 5 x 20 x 5 ml.

Not all pack-sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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The following information is only intended for healthcare professionals:

Use of lidocaine during pregnancy for local and regional anaesthesia

Use of lidocaine for epidural, pudendal, caudal or paracervical block may cause varying degrees of foetal and neonatal toxicity (e.g. bradycardia, hypotonia or respiratory depression). An accidental subcutaneous injection of lidocaine in the fetus during paracervical or perineal block may cause apnoea, hypotension and convulsive fits and may thus put the newborn at vital risk.

In general lidocaine in strengths of 10 mg/ml should be preferred during pregnancy.