Package leaflet: Information for the user
1% w/v Lidocaine Hydrochloride Injection BP
Lidocaine hydrochloride monohydrate

Read all of this leaflet carefully before you start using this medicine because it contains important information.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 1% w/v Lidocaine Hydrochloride Injection BP is and what it is used for

Lidocaine is a locally and regionally acting anaesthetic.

It is used to numb a defined body area before a surgical operation.

This medicine may be used in adults, adolescents and children over 2 years of age.

2. What you need to know before you use 1% w/v Lidocaine Hydrochloride Injection BP

You must not be given 1% w/v Lidocaine Hydrochloride Injection BP

- if you are allergic to lidocaine or similar substances that are also used as local anaesthetics or to 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 (hypovolaemia)
  - compromised blood clotting function (coagulopathy)
  - increased pressure within the skull
  - bleeding within the skull or within the spine.

[1]Epidural 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 anaesthesia[1].
- 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 administered in the head and neck region.

Other medicines and 1% w/v Lidocaine Hydrochloride Injection BP

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 1% w/v Lidocaine Hydrochloride Injection BP 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 treatment of irregular heartbeat
- 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)
- phenytoin, carbamazepine or primidone that are medicines for the treatment of epilepsy
- phenobarbital, which is used in general anaesthesia to make you sleep

- 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

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 is 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.

1% w/v Lidocaine Hydrochloride Injection BP contains sodium

5ml ampoule
This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium free'.

10 ml ampoule
This medicine contains 28.3 mg sodium (main component of cooking/table salt) in each ampoule. This is equivalent to 1.4% of the recommended maximum daily dietary intake of sodium for an adult.

20 ml ampoule
This medicine contains 56.6 mg sodium (main component of cooking/table salt) in each ampoule. This is equivalent to 2.8% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use 1% w/v Lidocaine Hydrochloride Injection BP

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
- 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
For local and regional anaesthesia in children only a low strength of this medicine (0.5% w/v) should be used. To achieve a complete motor block, a higher strength (1 % w/v) may be required.

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.

The dosing for adolescents should be adjusted carefully according to current guidelines and the dosage will be calculated individually according to the age, body weight and the nature of the procedure.

There are insufficient data to support the safety and efficacy of lidocaine in children younger than two years of age.

If you received more 1% w/v Lidocaine Hydrochloride Injection BP 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.

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 1% w/v Lidocaine Hydrochloride Injection BP than you should').

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 colour

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)
- an affection of eyelids, eye muscles and iris, called Horner's syndrome. It occurs after epidural anaesthesia or application in the head/neck region.
- shivering, deafness, or trauma
- transient irritation of the nerve roots due to spinal anaesthesia.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland:
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta:
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. How to store 1% w/v Lidocaine Hydrochloride Injection BP

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 1% w/v Lidocaine Hydrochloride Injection BP contains

- The active substance is lidocaine hydrochloride.

  One ml of the solution for injection contains 10 mg of lidocaine hydrochloride monohydrate.
  One ampoule of 5 ml contains 50 mg of lidocaine hydrochloride monohydrate.
  One ampoule of 10 ml contains 100 mg of lidocaine hydrochloride monohydrate.
  One ampoule of 20 ml contains 200 mg of lidocaine hydrochloride monohydrate.

- The other ingredients are
  sodium chloride, sodium hydroxide and water for injections

What 1% w/v Lidocaine Hydrochloride Injection BP looks like and contents of the pack

1% w/v Lidocaine Hydrochloride Injection BP is a solution for injection.
It is a clear, colourless solution of the aforementioned ingredients in water.

It comes in polyethylene plastic Mini Plasco ampoules holding 5 ml, 10 ml or 20 ml.
It is supplied in packs of 20 ampoules of each size.

Not all pack-sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Marketing Authorisation number:
PA0736/044/001 (Ireland)
MA223/00703 (5 ml, Malta)

MA223/00704 (10 ml, Malta)
MA223/00705 (20 ml, Malta)

This leaflet was last revised in 11.2025

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 foetus during paracervical or perineal block may cause apnoea, hypotension and convulsive fits and may thus put the new-born at vital risk.

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

For further detailed information especially about dosage and method of administration please refer to the summary of product characteristics.