Package leaflet: Information for the patient

Lidocaine hydrochloride Noridem 10 mg / mL (1 % 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, pharmacist or nurse.
- 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, 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 hydrochloride Noridem 10 mg / mL (1 % w/v) is and what it is used for
2. What you need to know before you are given Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v)
3. How Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v) is given
4. Possible side effects
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1. What Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v) is and what it is used for

Lidocaine hydrochloride Noridem 10 mg / mL 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 Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v)'). It is of special note that there are only limited data available on the use of this medicine in children under 2 years.

2. What you need to know before you are given Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v)

You must not be given Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v)

- if you are allergic to lidocaine hydrochloride 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 epidural or spinal anaesthesia (application of the anaesthetic to the spinal cord) if you have:
- uncorrected blood volume deficit (low blood volume - hypovolaemia)
- decreased blood clotting (coagulopathy)
- increased pressure within the skull
- bleeding within the skull or spine.

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.

You will 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 lungs
- diseases of the liver and kidneys
- an autoimmune disease leading to muscle weakness *(Myasthenia gravis)*
- severe shock
- any condition that may lead to an increased risk of fits and seizures (epilepsy)

Your doctor will take into account, especially when you are an elderly patient, that you may experience low blood pressure as a complication of spinal and epidural anaesthesia (application of the anaesthetic to the spinal cord).

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 Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v)

Tell your doctor or pharmacist 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 P 450 1A2 and 3A4). This is done to avoid interactions between Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v) and other medicines you are taking.

In particular, tell your doctor or pharmacist if you are taking any of the following:
- some heart medicines, such as beta blockers (e.g. metoprolol, propranolol) or calcium channel blockers (e.g. amiodarone)
- antiarrhythmics - medicines for treatment of irregular heartbeat
- medicines that narrow your blood vessels (vasoconstrictors, e.g. epinephrine, norephinephrine)
- cimetidine, a medicine used to treat heartburn
- antivirals – (i.e. medicines for the treatment of HIV)
- sleeping pills and medicines that reduce your level of consciousness (sedatives) or cause drowsiness
- phenobarbital, phenytoin, carbamazepine or primidone that are medicines for the treatment of epilepsy
- 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.

<u>Pregnancy and breast-feeding</u>

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 using 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 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.

Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v) contains sodium

<u>2 mL and 5 mL ampoules:</u>
This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.

<u>10 mL and 20 mL ampoules:</u>
This medicine contains 26.8 – 27.4 mg sodium (main component of cooking/table salt) in each 10 mL ampoule and 53.6 – 54.9 mg sodium in each 20 mL ampoule. This is equivalent to 1.34 – 1.37 % and 2.68 – 2.74 % of the recommended maximum daily dietary intake of sodium for an adult, respectively.

3. How Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v) is given

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.

<u>Adults</u>
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).

<u>Use in children and adolescents</u>
The dose for children and adolescents 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. In order to perform a special technique called complete motor block, your doctor may require a higher strength (1 % w/v).

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The following information is intended for healthcare professionals only:

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 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.

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

In certain groups of people the dose of lidocaine given is reduced. 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.

If you received more Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v) than you should

Whether you develop symptoms of an overdose or not depend 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 heartbeator irregular heartbeat
- 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.

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 Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v) 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

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 such as tickling, tingling, burning, pricking, or numbness
- headaches accompanied by sensitivity to sunlight (photophobia) and hearing (tinnitus)
- a drop of your eyelid(s) combined with the narrowing of your pupils and sometimes decreased sweating, (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 via 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 Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v)

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.

The solution for injection is to be administered immediately after opening the container.

Containers are for single use only. Discard the container and any unused contents once opened.

The solution for injection is only to be used if it is clear, colourless, and practically free from particles and the container and its closure are undamaged.

After dilution, chemical and physical in use stability has been demonstrated for 24 hours both at 25°C and 2 to 8°C if diluted in sodium chloride 9 mg / mL (0.9 %) solution or 50 mg / mL glucose (5 %) solution. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

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 hydrochloride Noridem 10 mg / mL (1 % w/v) contains

- The active substance is lidocaine hydrochloride.

Each mL of the solution contains 10 mg lidocaine hydrochloride.
Each ampoule of 2 mL contains 20 mg of lidocaine hydrochloride.
Each ampoule of 5 mL contains 50 mg of lidocaine hydrochloride.
Each ampoule of 10 mL contains 100 mg of lidocaine hydrochloride.
Each ampoule of 20 mL contains 200 mg of lidocaine hydrochloride.

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

What Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v) looks like and contents of the pack

Lidocaine hydrochloride Noridem 10 mg / mL (1 % w/v) Solution for injection is a clear and colourless solution.
Polypropylene ampoules of 2 mL, 5 mL, 10 mL or 20 mL. Each carton contains 5, 10, 20, 50 or 100 ampoules.

Not all pack sizes may be marketed.

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