

Package leaflet: Information for the user

Lidocaine Grindeks 20 mg/ml 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 Grindeks is and what it is used for
2. What you need to know before you are given Lidocaine Grindeks
3. How Lidocaine Grindeks is given
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1. What Lidocaine Grindeks is and what it is used for

Lidocaine Grindeks is a local anaesthetic. It is used to numb parts of the body during small surgical procedures in adults. It stops the nerves from being able to pass pain messages to the brain and so stops you feeling pain. It starts to work a few minutes after being injected and slowly wears off when the surgical procedure is over.

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

Do not use Lidocaine Grindeks

- if you are allergic to lidocaine hydrochloride, to local anaesthetics of the amide type or any of the other ingredients of this medicine (listed in section 6);
- if you have very low blood pressure, or if you have lost too much blood or other body fluids or your heart is unable to pump enough blood for other reasons, you should not get Lidocaine Grindeks injected into your spine.

Warnings and precautions

Talk to your doctor or nurse before having Lidocaine Grindeks injection if:

- you are elderly or in a generally debilitated condition,
- you have heart problems such as a slow or irregular heart beat or heart failure,
- you suffer from lung or breathing disorder,
- you have liver or kidney problems,
- you suffer from epilepsy,
- you are treated with medicines used to treat an irregular heart beat (for example, amiodarone),
- you have inflammation or infection in the area to be injected,
- you have a rare disease of the blood pigment called porphyria or anyone in your family has it.

If you are not sure if any of the above applies to you, talk to your doctor before having a Lidocaine Grindeks injection.

Children and adolescents

Other pharmaceutical forms/strengths are more appropriate for administration in children and adolescents.

Other medicines and Lidocaine Grindeks

Tell your doctor if you are using, have recently used or might use any other medicines.

In particular, tell your doctor if you are using any of the following medicines:

- other local anaesthetics,
- medicines used to treat an irregular heart beat (arrhythmia) such as amiodarone,
- medicines to treat stomach or duodenal ulcer such as cimetidine.

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 for advice before you are given this medicine.

Driving and using machines

Depending on dose and method of administration, Lidocaine Grindeks can have a temporary effect on movement and coordination.

3. How Lidocaine Grindeks is given

Lidocaine Grindeks will be given to you by a doctor. It will be given to you as an injection into a vein, a muscle, under the skin, or into the epidural space near the spinal cord.

The dose that your doctor gives you will depend on the type of pain relief that you need. It will also depend on your body size, age, physical condition and the part of your body that the medicine is being injected into. You will be given the smallest dose possible to produce the required effect.

Intravenous regional anaesthesia

Arm: 5-10 ml of solution (100-200 mg of lidocaine hydrochloride) injected into your vein.

Leg: 10 ml of solution (200 mg of lidocaine hydrochloride) injected into your vein.

Nerve blocks

1-2 ml of solution (20-40 mg of lidocaine hydrochloride) injected into or around a nerve.

Epidural anaesthesia (an injection is performed along the spine)

Lumbar analgesia: 12.5-20 ml of solution (250-400 mg of lidocaine hydrochloride).

Chest anaesthesia: 10-15 ml of solution (200-300 mg of lidocaine hydrochloride).

Sacral (at the bottom of the spine) surgery analgesia: 20 ml of solution (400 mg of lidocaine hydrochloride).

Sacral analgesia during labour: 10-15 ml of solution (200-300 mg of lidocaine hydrochloride).

The recommended maximum single dose of Lidocaine Grindeks is 400 mg.

The dose should be reduced for patients in poor general condition.

Lidocaine Grindeks injection will usually be given near the part of the body to be operated on.

Use in children and adolescents

Other forms/strengths of this medicine may be more suitable for children and adolescents; ask your doctor or nurse.

If you have been given more Lidocaine Grindeks than you should

The doctor treating you is trained to deal with serious side effects from getting too much Lidocaine Grindeks.

The first signs of being given too much Lidocaine Grindeks are usually as follows:

- convulsions,

- restlessness,
- feeling dizzy or light-headed,
- nausea,
- numbness or tingling sensations of the lips and around the mouth,
- problems with sight.

If any of these happen to you, or you think you have received too much Lidocaine Grindeks, tell your doctor immediately.

More serious side effects from being given too much Lidocaine Grindeks may follow, such as balance and coordination disorders, auditory changes, euphoria, confusion, problems with your speech, paleness, sweating, trembling, convulsions, effects on your heart and blood vessels, loss of consciousness, coma and stopping breathing for a short while (apnoea).

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

4. Possible side effects

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

Severe allergic reactions are rare. If you have a severe allergic reaction, tell your doctor immediately. The signs may include sudden onset of:

- swelling of your face, lips, tongue or throat; this may make it difficult to swallow,
- severe or sudden swelling of your hands, feet and ankles,
- difficulty breathing,
- severe itching of the skin (with raised lumps),
- fever,
- fall in blood pressure.

Other possible side effects:

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

- Low blood pressure
- Nausea

Common (may affect up to 1 in 10 people)

- Pins and needles
- Dizziness
- Slow heart beat
- High blood pressure
- Vomiting

Uncommon (may affect up to 1 in 100 people)

- Convulsions
- Numbness of the tongue or tingling sensations around the mouth
- Ringing in the ears or being sensitive to sound
- Visual disturbances
- Loss of consciousness
- Tremor
- Drowsiness
- Light-headedness
- Tinnitus
- Feeling of intoxication
- Difficulty in speaking

Rare (may affect up to 1 in 1000 people)

- Hypersensitive reactions such as hives (urticaria), rash, angioedema and in severe cases anaphylactic shock
- Changes in sensations or muscle weakness (neuropathy)
- Inflammation of a membrane surrounding the spinal cord (arachnoiditis) which can cause pain in the lower back, or pain, numbness or weakness in the legs
- Double vision
- Irregular or stopped heart beat
- Slowed or stopped breathing

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

<To be completed nationally>

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

5. How to store Lidocaine Grindeks

Do not freeze.

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

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any particles in the ampoule.

Solution should be used immediately after opening.

Any unused product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What Lidocaine Grindeks contains

- The active substance is lidocaine hydrochloride.

1 ml of solution contains 20 mg lidocaine hydrochloride.

Each 5 ml ampoule contains 100 mg lidocaine hydrochloride.

- The other ingredients (excipients) are sodium chloride, sodium hydroxide (for pH adjustment), water for injections.

What Lidocaine Grindeks looks like and contents of the pack

A clear, colourless or slightly yellowish liquid, free from visible particles.

5 ml clear colourless glass ampoules. Pack size: 10 ampoules.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden: Lidocaine Grindeks 20 mg/ml injektionsvätska, lösning

Hungary: Lidocaine Grindeks 20 mg/ml oldatos injekció
Poland: Lidocaine Grindeks 20 mg/ml roztwór do wstrzykiwań
Romania: Lidocaină Grindeks 20 mg/ml soluție injectabilă
Iceland: Lidocaine Grindeks 20 mg/ml stungulyf, lausn
Belgium: Lidocaine Grindeks 20 mg/ml oplossing voor injectie/
solution injectable/Injektionslösung
The Netherlands: Lidocaine Grindeks 20 mg/ml oplossing voor injectie

This leaflet was last revised in 2018-09-19

The following information is intended for medical or healthcare professionals only:

Lidocaine hydrochloride has been reported to be incompatible in solutions with amphotericin B, sulfadiazine sodium, methohexital sodium, cefazolin sodium, or phenytoin sodium.

Acid stable drugs such as adrenaline hydrochloride, noradrenaline acid tartrate, or isoprenaline may begin to deteriorate within several hours of mixture with lidocaine hydrochloride as lidocaine solutions may raise the pH of the final solution above the maximum pH for their stability.

Alkalisiation can result in precipitation since lidocaine is only slightly soluble in pH over 6.5.