Package leaflet: Information for the user

Lydagriks 10 mg/ml solution for injection
Lydagriks 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.
- 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 [Invented name] is and what it is used for

[Invented name] contains the active substance lidocaine, which is a local anaesthetic. It is used to numb parts of the body during small surgical procedures. It temporarily stops the nerve from being able to pass pain messages to the brain in the area where it is injected.

[Invented name] 10 mg/ml can be used in adults and children over 1 year of age.
[Invented name] 20 mg/ml can be used in adults.

2. What you need to know before you are given [Invented name]

Do not use [Invented name]
- if you are allergic to lidocaine, to local anaesthetics of the amide type or any of the other ingredients of this medicine (listed in section 6).

Do not use [Invented name] for epidural anaesthesia if you have
- very low blood preassure
- a life-threatening condition in which due to heart problems your heart becomes unable to pump enough blood to meet your body's needs (cardiogenic shock)
- a life-threatening condition in which severe blood or other fluid loss makes the heart unable to pump enough blood to meet your body's needs (hypovolemic shock).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using [Invented name]:
- if you are elderly or in a generally debilitated condition since the dose should be reduced
- if you have any heart problems such as a slow or irregular heartbeat (heart block, AV block)
- if you have liver or kidney problems condtition since the dose should be reduced
- in back anaesthesia (epidural anaesthesia), as the blockage of central nerves can cause serious side effects
- in the eye, as in rare cases the medicine may cause transient or permanent side effects
- in infusion directly to the joint space (intra-articular infusion), as it may cause rapid loss of joint cartilage (chondrolysis)
- if you have a disease called acute porphyria.

Other medicines and [Invented name]
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription.

[Invented name] can affect or be affected by other medicines, such as:
- other local anaesthetics
- medicines for disturbed heart rhythm (so-called antiarrhythmics)
- cimetidine (medicine for stomach ulcers) and beta-blockers (medicines for high blood pressure, among others)

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.

Lidocaine passes the placenta and reaches the foetus. However, there is no evidence that lidocaine causes negative effects on the foetus, even if the risk is not fully known.

Your doctor will weigh the benefits against the risks of using this medicine for short term treatment during pregnancy and at delivery. If the medicine is used in the cervix, the doctor will closely monitor the baby's pulse.

Lidocaine passes into breast milk, but it is unlikely to have any effects on the breastfed baby and you can therefore breast-feed after treatment with this medicine.

Driving and using machines
Depending on dose and where you received [Invented name], it can have temporary effect on your ability to drive or use machinery. You should not perform these activities until normal function is fully restored.

[Invented name] contains sodium chloride

10 mg/ml solution for injection
- 5 ml ampoule: This medicine contains less than 1 mmol sodium (23 mg) per 5 ml ampoule, that is to say essentially 'sodium-free'.
- 10 ml ampoule: This medicine contains 27.8 mg sodium (main component of cooking/table salt) in each 10 ml ampoule. This is equivalent to 1.4% of the recommended maximum daily dietary intake of sodium for an adult.
- 20 ml vial: This medicine contains 55.6 mg sodium (main component of cooking/table salt) in each 20 ml vial. This is equivalent to 2.8% of the recommended maximum daily dietary intake of sodium for an adult.
- 50 ml vial: This medicine contains 139 mg sodium (main component of cooking/table salt) in each 50 ml vial. This is equivalent to 7% of the recommended maximum daily dietary intake of sodium for an adult.

20 mg/ml solution for injection
- 2 ml ampoule:This medicine contains less than 1 mmol sodium (23 mg) per 2 ml ampoule, that is to say essentially 'sodium-free'.
- 5 ml ampoule: This medicine contains less than 1 mmol sodium (23 mg) per 5 ml ampoule, that is to say essentially 'sodium-free'.
- 10 ml ampoule: This medicine contains 23.8 mg sodium (main component of cooking/table salt) in each 10 ml ampoule. This is equivalent to 1.2% of the recommended maximum daily dietary intake of sodium for an adult.
- 20 ml vial: This medicine contains 47.6 mg sodium (main component of cooking/table salt) in each 20 ml vial. This is equivalent to 2.4% of the recommended maximum daily dietary intake of sodium for an adult.

- 50 ml vial: This medicine contains 119 mg sodium (main component of cooking/table salt) in each 50 ml vial. This is equivalent to 6% of the recommended maximum daily dietary intake of sodium for an adult.

3. How [Invented name] is given

[Invented name] will be given to you by a doctor. It depends on the type of anaesthetic you need, the area to be anaesthetized, and the duration of the anaesthetic. It will be given to you as an injection into a vein, 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.

Use in children and adolescents
This medicine can be used in children and the treatment will be individually adjusted for each child.

If you use more [Invented name] than you should
The medicine will be given to you by health care staff and it is unlikley that you will recive too much lidocaine.

The staff treating you is trained to deal with serious side effects from getting too much of the medicine. The first signs of being given too much lidocaine are usually as follows:
- convulsions,
- 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 medicine, tell your doctor or nurse immediately.

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

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

4. Possible side effects

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

Very common (may affect more than 1 in 10 people)
- Low blood pressure
- Nausea

Common (may affect up to 1 to 10 people)
- High blood pressure
- Dizziness
- Pins and needles
- Slow heartbeat
- Vomiting

Uncommon (may affect up to 1 in 100 people)
- Signs of toxic reactions in the central nervous system, such as:
  - Cramps
  - Numbness of the tongue or tingling sensations around the mouth
  - Increased sensitivity to sound
  - Visual disturbances
  - Tremor
  - Feeling of intoxication
  - Tinnitus
  - Difficulty in speaking
  - Loss of consciousness

Rare (may affect up to 1 in 1 000 people)
- Allergic reactions with symptoms such as hives (urticaria) and rash and in severe cases anaphylactic shock
- Irregular or stopped heartbeat (cardiac arrythmias, cardiac arrest)
- Slowed or stopped breathing
- 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

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

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 ampoule, vial label and carton after "EXP". The expiry date refers to the last day of that month.

Do not freeze.
Do not store above 25 °C.
Do not use this medicine if you notice any particles in the ampoule or vial.
Solution should be used immediately after opening.

Do not throw away any medicines via wastewater or household waste. Any unused medicinal product or waste material should be disposed of in accordance with local requirments.

6. Contents of the pack and other information

What [Invented name] contains
- The active substance is lidocaine hydrochloride.

10 mg/ml solution for injection
1 ml of solution for injection contains 10 mg lidocaine hydrochloride.

One ampoule of 5 ml contains 50 mg lidocaine hydrochloride.
One ampoule of 10 ml contains 100 mg lidocaine hydrochloride.
One vial of 20 ml contains 200 mg lidocaine hydrochloride.

One vial of 50 ml contains 500 mg lidocaine hydrochloride.

20 mg/ml solution for injection
1 ml of solution for injection contains 20 mg lidocaine hydrochloride.

One ampoule of 2 ml contains 40 mg lidocaine hydrochloride.
One ampoule of 5 ml contains 100 mg lidocaine hydrochloride.
One ampoule of 10 ml contains 200 mg lidocaine hydrochloride.
One vial of 20 ml contains 400 mg lidocaine hydrochloride.
One vial of 50 ml contains 1000 mg lidocaine hydrochloride.

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

What [Invented name] looks like and contents of the pack
A clear, colourless or slightly yellowish solution free from visible particles.

10 mg/ml solution for injection
Ampoules
5 ml or 10 ml clear Type I hydrolytic resistant class colourless borosilicate glass ampoules with one point cut are used for packaging. Ampoules are marked with a colour ring code. 5 or 10 ampoules are packed in a cardboard box.
Vials
20 ml and 50 ml injection vials of Type I clear borosilicate moulded glass with crimp neck. The vials are closed with 20 mm bromobutyl rubber stoppers and with 20 mm aluminium flip-off seals. 10 vials are packed in a cardboard box.

20 mg/ml solution for injection
Ampoules
2 ml, 5 ml or 10 ml clear Type I hydrolytic resistant class colourless borosilicate glass ampoules with one point cut are used for packaging. Ampoules are marked with a colour ring code. 5 or 10 ampoules are packed in a cardboard box.
Vials
20 ml and 50 ml injection vials of Type I clear borosilicate moulded glass with crimp neck. The vials are closed with 20 mm bromobutyl rubber stoppers and with 20 mm aluminium flip-off seals. 10 vials are packed in a cardboard box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	Lidocaine Grindeks 10 mg/ml Injektionslösung Lidocaine Grindeks 20 mg/ml Injektionslösung
Belgium	Lydagriks 10 mg/ml oplossing voor injectie Lydagriks 10 mg/ml solution injectable Lydagriks 10 mg/ml Injektionslösung Lydagriks 20 mg/ml oplossing voor injectie Lydagriks 20 mg/ml solution injectable Lydagriks 20 mg/ml Injektionslösung
Bulgaria	Lidocaine Grindeks 10 mg/ml инжекционен разтвор

	Lidocaine Grindeks 20 mg/ml инжекционен разтвор
Finland	Lidocaine Grindeks 10 mg/ml injektioneste Lidocaine Grindeks 20 mg/ml injektioneste
France	Lidocaine Grindeks 10 mg/ml SANS CONSERVATEUR solution injectable Lidocaine Grindeks 20 mg/ml SANS CONSERVATEUR solution injectable
Germany	Lidocain Grindeks 10 mg/ml Injektionslösung Lidocain Grindeks 20 mg/ml Injektionslösung
Hungary	Lydagriks10 mg/ml oldatos injekció Lydagriks 20 mg/ml oldatos injekció
Italy	Lidocaina Grindeks
Latvia	Lisendum10 mg/ml šķīdums injekcijām Lisendum 20 mg/ml šķīdums injekcijām
Poland	Lydagriks
Portugal	Lidocaine Grindeks 10 mg/ml solução injetável Lidocaine Grindeks 20 mg/ml solução injetável
Romania	Livohep 10 mg/ml soluție injectabilă Livohep 20 mg/ml soluție injectabilă
Sweden	Lydagiks

This leaflet was last revised in 2024-05-16.

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

The medicinal product must not be stored in contact with metals, e.g. needles or metal parts of syringes as dissolved metal ions may cause swelling at the site of injection.

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