Package leaflet: Information for the user

Lidocaine Accord 10 mg/ml solution for injection
Lidocaine Accord 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 or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet See section 4.

What is in this leaflet:

1. What Lidocaine Accord is and what it is used for

Lidocaine Accord is a local anaesthetic. It is used to numb parts of the body during small surgical procedures. 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.

Lidocaine Accord 10 mg/ml is prescribed for adults and children older than 1 year.
Lidocaine Accord 20 mg/ml is prescribedfor adults and adolescents older than 12 years.

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

You should not be given this medicine:
- if you are allergic to lidocaine hydrochloride or other local anaesthetics similar to lidocaine 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 Accord injected into your spine.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before using Lidocaine Accord
- if you are elderly or in a generally debilitated condition
- if you suffer from any heart problems such as a very high blood pressure, certain heart abnormalities, slow or irregular heart beat or heart failure.
- if you have reduced or insufficient oxygen supply (hypoxia) or too much acid in the body fluids (acidosis)
- if you suffer from impaired respiratory depression
- if you suffer from any liver disease or severe kidney dysfunction .

- If you are being treated with a class III anti-arrhythmic medication, such as amiodarone.
- if you suffer from fits (epilepsy).
- if you have inflammation or infection in the area to be injected.
- if you have porphyria (a disease caused by an underlying disturbance in the production of the red pigment in blood).

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

Other medicines and Lidocaine Accord
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor if you are taking any of the following medicines:
- other local anaesthetics.
- medicines used in the treatment of stomach or duodenal ulcers (e.g. cimetidine).
- medicines used to treat irregular heart beat (e.g. amiodarone).
- Medicines used for the treatment of high blood pressure (e.g. beta blockers)

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 or pharmacist for advice before taking this medicine.
It is unlikely that the use of Lidocaine Accord will affect the foetus. When using nearby the cervix, your doctor must carefully monitor the foetal pulse.

Lidocaine Accord is excreted into breast milk, but is not likely that breast-feeding children will be affected.

Driving and using machines
Depending on dose and administration, Lidocaine Accord can have temporary effect on your ability to drive or use machinery.
Ask your doctor when it would be safe to resume these activities.

Lidocaine Accord contains Sodium
Each ml of solution for injection contains approximately 0.118 mmol sodium (if the strength 10 mg/ml is used) or 0.082 mmol sodium (if the strength 20 mg/ml is used). To be taken into consideration by patients on a sodium controlled diet.

3. How Lidocaine Accord is given

Lidocaine Accord 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.

Use in children and adolescents
The dose should be reduced in children and patients in reduced general

condition.

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

If you have given too much Lidocaine Accord
Lidocaine Accord is usually administered in hospital in the operating theatre. You will be closely monitored. The doctor treating you is trained to deal with serious side effects from getting too much Lidocaine Accord.

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.

In case of overdose, symptoms of an overdose can occur, usually within 15-60 minutes. If Lidocaine Accord is accidentally injected into a blood vessel, symptoms of an overdose can occur immediately (within seconds or minutes).

A small overdose mainly affects your central nervous system. Adverse effects that do occur will disappear in most cases after stopping lidocaine administration.

The symptoms mainly affect the central nervous system and the cardiovascular system, and the first signs are usually numbness in the mouth and tongue, a feeling of intoxication, sensitivity to sound, tinnitus and visual disturbances. After that, you may have more serious symptoms, such as difficulty speaking clearly, muscle twitching or tremors, and eventually convulsions and unconsciousness. In addition, you may experience breathing difficulties. In severe cases, low blood pressure, slow heart rhythm, heart rhythm disturbances and even cardiac arrest can occur.

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.

4. Possible side effects

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

Tell your doctor or nurse immediately if you have a severe allergic reaction (anaphylactic shock). 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.

These side effects are rare (may affect up to 1 in 1000 people).

Other possible side effects:

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

Common (may affect up to 1 in10 people)
- Pins and needles
- Dizziness
-
- Slow heart beat (bradycardia) - High blood pressure (hypertension)
- Vomiting

Uncommon (may affect up to 1 in 100 people)
- Convulsions
- Numbness of the tongue or prickling, itching or tingling sensations around the mouth
- Ringing in the ears (tinnitus) or being sensitive to sound
- Visual disturbances
- Loss of consciousness
- Tremor
- Speech disorder (dysarthria)
- Drowsiness
- Light-headedness

Rare (may affect up to 1 in 1000 people)
- 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
- Peripheral nerve damage (damage to the nerves outside the central nervous system)
- Double vision
- Irregular or stopped heart beat (cardiac arrest)
- Slowed or stopped breathing (respiratory depression).

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 Lidocaine Accord

Keep this medicine out of the sight and reach of children.
This medicinal product does not require any special storage conditions.
Do not use this medicine after the expiry date which is stated on the ampoule/vial and carton label after EXP. The expiry date refers to the last day of that month.

For single use only, used immediately after first opening, discard any unused contents.

Do not use this medicine if you notice the contents are discoloured in any way.

The solution for injection should not be used if there are particles present.

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 Accord contains

The active substance is lidocaine hydrochloride.
Lidocaine Accord 10 mg/ml solution for injection: 1 ml of solution for injection contains 10 mg of lidocaine hydrochloride.
Lidocaine Accord 20 mg/ml solution for injection: 1 ml of solution for injection contains 20 mg of lidocaine hydrochloride.
The other ingredients are sodium chloride, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injections.

What Lidocaine Accord looks like and the contents of the pack

Lidocaine Accord is a clear, colourless, sterile solution for injection. It is available in two strengths, 10 mg/ml and 20 mg/ml.

Lidocaine Accord 10 mg/ml solution for injection is available in

Glass ampoules:	5 x 2 ml, 10 x 2 ml, 20 x 2 ml 5 x 5 ml, 10 x 5 ml, 20 x 5 ml 10 x 10 ml, 20 x 10 ml
Glass vials:	1 x 20 ml

Lidocaine Accord 20 mg/ml solution for injection is available in

Glass ampoules:	5 x 2 ml, 10 x 2 ml, 20 x 2 ml 5 x 5 ml, 10 x 5 ml, 20 x 5 ml 5 x 10ml, 10 x 10 ml, 20 x 10 ml
Glass vials:	1 x 20 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder
< To be completed nationally>

Manufacturer

< To be completed nationally>

< To be completed nationally>

This leaflet was last revised in
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The following information is intended for healthcare professionals only:

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.
For single use only, used immediately after first opening, discard any unused contents.

Do not use this medicine if you notice the contents are discoloured in any way. The solution for injection should not be used if there are particles present.

Method of administration
Lidocaine Accord should only be used by, or under the supervision of, doctors with experience of regional anaesthesia and resuscitative skills. Facilities for resuscitation should be available when administering local anaesthetics.

Please refer to the summary of product characteristics for posology information.