

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
2. What you need to know before you are given Lidocaine Accord
3. How Lidocaine Accord is given
4. Possible side effects
5. How to store Lidocaine Accord
6. Contents of the pack and other information

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.

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, 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 Accord injected into your spine.

Speak to your doctor if one of these applies to you before you are given this medicine.

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 slow or irregular heart beat or heart failure.
- If you suffer from lung or breathing disorder.
- if you suffer from any liver disease or kidney problems.
- if you suffer from fits (epilepsy).
- if you have inflammation or infection in the area to be injected.
- if you have porphyria (a rare inherited disease that affects the skin and

- nervous system).
- if you have problems with blood clotting
- if you are in the last three month of pregnancy

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.

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).

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.

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

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

The first signs of being given too much Lidocaine Accord 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 Accord, tell your doctor or nurse immediately.

More serious side effects from being given too much Lidocaine Accord 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.

Tell your doctor or nurse immediately if you have a severe allergic reaction (angioedema or 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 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 [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

Accord Healthcare Limited
Sage House, 319, Pinner Road, North Harrow,
Middlesex, HA1 4HF, United Kingdom

Wessling Hungary Kft
Budapest, Fóti út 56,
1047, Hungary

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

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

Country	Invented Name
SE	Lidocaine Accord
AT	Lidocain Accord 10 mg/ml, 20 mg/ml injektionslösung
BE	Lidocaine Accord 10 mg/ml, 20 mg/ml oplossing voor injectie / solution injectable/ injektionslösung
BG	Lidocaine Accord 10 mg/ml, 20 mg/ml solution for injection
CY	Lidocaine Accord 10 mg/ml, 20 mg/ml solution for injection
DE	Lidocain Accord 10 mg/ml Injektionslösung Lidocain Accord 20 mg/ml Injektionslösung
DK	Lidocain Accord 10 mg/ml, 20 mg/ml injektionsvæske, opløsning
EE	Lidocaine Accord
ES	Lidocaina Accord 10 mg/ml, 20 mg/ml solución inyectable
FI	Lidocaine Accord 10 mg/ml, 20 mg/ml injektioneste, liuos
FR	Lidocaine Accord 10 mg/ml, 20 mg/ml solution injectable
IT	Lidocaina Accord
LT	Lidocaine Accord 10 mg/ml, 20 mg/ml injekcinis tirpalas
LV	Lidocaine Accord 20 mg/ml šķīdums injekcijām

NL	Lidocaine Accord 10 mg/ml, 20 mg/ml oplossing voor injectie
NO	Lidocaine Accord 10 mg/ml, 20 mg/ml injeksjonsvæske, oppløsning
PL	Lidocaine Accord 10 mg/ml, 20 mg/ml
PT	Lidocaína Accord 10 mg/ml, 20 mg/ml

This leaflet was last revised in 02 July 2019.

< To be completed nationally >

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.