



712223

Package leaflet: Information for the patient

Lidocaine 10 mg/ml (1% w/v) with Adrenaline (Epinephrine) 1:200 000 solution for injection
Lidocaine 20 mg/ml (2% w/v) with Adrenaline (Epinephrine) 1:200 000 solution for injection
lidocaine hydrochloride / adrenaline



Read all of this leaflet carefully before you are given 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lidocaine with Adrenaline is and what it is used for
2. What you need to know before you are given Lidocaine with Adrenaline
3. How Lidocaine with Adrenaline is given to you
4. Possible side effects
5. How to store Lidocaine with Adrenaline
6. Contents of the pack and other information

1.What Lidocaine with Adrenaline is and what it is used for

Lidocaine with Adrenaline is used to numb (anaesthetise) part of the body for surgical operations or to provide pain relief. It temporarily blocks the nerve signals in the area where it is injected from being able to pass pain messages to the brain, which prevents you from feeling pain.

Lidocaine 10 mg/ml (1% w/v) with Adrenaline (Epinephrine) 1:200 000 can be used in adults and children above 1 year of age to:

- numb (anaesthetise) the area of the body where surgery is to be performed.
- provide pain relief in labour, after surgery or after acute injury.
- treat certain types of chronic pain.

Lidocaine 20 mg/ml (2% w/v) with Adrenaline (Epinephrine) 1:200 000 can be used in adults and adolescents above 12 years to:

- numb (anaesthetise) the area of the body where surgery is to be performed.
- provide pain relief in labour, after surgery or after acute injury.
- treat certain types of chronic pain.

Lidocaine with adrenaline contains two different medicines: lidocaine and adrenaline (epinephrine). Each of these works in a different way.

Lidocaine belongs to a group of medicines called local anaesthetics. These medicines numb (anaesthetise) parts of the body.

Adrenaline (epinephrine) belongs to a group of medicines called vasoconstrictors. These medicines make the blood vessels where the injection is given narrower. This means you will bleed less and the effects of the medicine will last longer.

2. What you need to know before you are given Lidocaine with Adrenaline

Lidocaine with Adrenaline should not be given:

- if you are allergic to lidocaine, adrenaline or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to any other local anaesthetics.

You must not be given lidocaine with adrenaline if any of the above apply to you. If you are not sure, talk to your doctor or nurse before you are given it.

Warnings and precautions

Talk to your doctor or nurse before Lidocaine with Adrenaline is given to you:

- if you have severe high blood pressure or heart problems such as a slow heart beat.
- if you have been told that you have hypovolaemia (decreased volume of blood).
- if you have liver or kidney problems.
- if you have difficulty breathing.
- if you have epilepsy.
- if you have diabetes.
- if you have thyroid problems.
- if you have ever had a stroke.
- if you have an infection or inflammation at the site where the injection is to be given.
- if you have ever been told that you have a rare disease of the blood pigment called “porphyria” or anyone in your family has it.
- if you have reduced blood supply to the brain.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before having lidocaine with adrenaline.

Children and adolescents

Lidocaine 10 mg/ml (1% w/v) with Adrenaline (Epinephrine) 1:200 000 should not be used for children below 1 year of age.

Lidocaine 20 mg/ml (2% w/v) with Adrenaline (Epinephrine) 1:200 000 should not be used in children less than 12 years of age.

Other medicines and Lidocaine with Adrenaline

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

This includes medicines that you buy without a prescription and herbal medicines. This is because lidocaine with adrenaline can affect the way some medicines work and some medicines can have effect on lidocaine with adrenaline.

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

- other local anaesthetics.
- other medicines that contain adrenaline.
- halothane (a general anaesthetic).
- medicines used to threat an uneven heart beat (arrhythmia) such as amiodarone.
- beta-blockers medicines such as propranolol.
- butyrophenone medicines for sickness, such as domperidone.
- other butyrophenone medicines for mental problems, such as haloperidol.
- phenothiazine medicines for mental problems, such as chlorpromazine.
- medicines for depression such as monoamine oxidase inhibitors (MAOIs) and tricyclic antidepressants.
- medicines that induce labour.
- 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 or nurse for advice before being given this medicine.

Driving and using machines

This medicine may make you feel sleepy and affect the speed of your reactions. After you have been given lidocaine with adrenaline, you should not drive or use tools or machines until the next day.

Lidocaine with Adrenaline contains sodium and sodium metabisulfite (E223).

Lidocaine with Adrenaline contains 2.48 mg of sodium (main component of cooking/table salt) per ml. This is equivalent to 1.24% of the recommended maximum daily dietary intake of sodium for an adult.

Presence of sodium metabisulfite may rarely cause severe hypersensitivity (allergic) reactions and bronchospasm.

3. How Lidocaine with Adrenaline is given to you

This medicine will be given to you by your doctor or nurse. It will be given to you as an injection. 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.

This medicine will usually be given near the part of the body to be operated on. It stops the nerves from being able to pass pain messages to the brain. It will stop you feeling pain. It will start to work a few minutes after being injected and will slowly wear off when the medical procedure is over.

Use in children and adolescents

Lidocaine 10 mg/ml (1% w/v) with Adrenaline (Epinephrine) 1:200 000 should not be used for children below 1 year of age.

Lidocaine 20 mg/ml (2% w/v) with Adrenaline (Epinephrine) 1:200 000 should not be used in children less than 12 years of age because of safety concerns.

If you have been given too much Lidocaine with Adrenaline

Serious side effects from getting too much lidocaine with adrenaline need special treatment and the doctor treating you is trained to deal with these situations. The first signs of being given too much lidocaine with adrenaline are usually as follows:

- Feeling dizzy or light-headed.
- Numbness of the lips and around the mouth.
- Numbness of the tongue.
- Hearing problems.
- Problems with your sight (vision).

To reduce the risk of serious side effects, your doctor will stop giving you lidocaine with adrenaline as soon as these signs appear. This means that if any of these happen to you, or you think you have received too much lidocaine with adrenaline, tell your doctor immediately.

More serious side effects from being given too much lidocaine with adrenaline include problems with your speech, irrational behaviour, twitching of your muscles, fits (seizures), effects on your heart and blood vessels, loss of consciousness, coma and stopping breathing for a short while (apnoea).

4. Possible side effects

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

If you suffer from any of the following symptoms seek **immediately medical attention:**

Severe allergic reactions; signs may include sudden onset of swelling of your face, lips, tongue or throat which may make it difficult to swallow, severe or sudden swelling of your hands, feet and ankles, difficulty breathing (you may find it more difficult to breathe or your breathing may stop) or severe itching of the skin (with raised lumps).

Nerve damage; signs may include gradual onset of numbness, prickling or tingling and/or muscle weakness in your feet or hands, which can spread upward into your legs and arms.

Arachnoiditis (inflammation of a membrane that surrounds the spinal cord); signs may include a stinging or burning pain in the lower back or legs and tingling, numbness or weakness in the legs.

If you experience any of the following side effects, or notice any other unusual effects not mentioned in this leaflet, tell your doctor immediately:

Common (may affect up to 1 in 10 people)

- Low blood pressure.
- High blood pressure.
- Feeling sick (nausea) or being sick (vomiting).
- Pins and needles.
- Feeling dizzy.
- Slow heart beat.

Uncommon (may affect up to 1 in 100 people)

- Ringing in the ears (tinnitus) or being sensitive to sound.
- Difficulty in speaking.
- Numbness of the tongue or around the mouth.

- Fits (seizures).
- Feeling sleepy.
- Shakiness.
- Blurred vision.

Rare (may affect up to 1 in 1,000 people)

- Uneven heart beat (arrhythmias).
- Double vision.

Possible side effects seen with other local anaesthetics which might also be caused by lidocaine with adrenaline include:

- Damaged nerves which may cause permanent problems.

Other possible side effects:

- Numbness where the injection is given. This will go away slowly.

Reporting of side effects

If you get any side effects, talk to your doctor 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 with Adrenaline

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

Store in a refrigerator (2°C – 8°C). Keep the ampoule in the outer carton in order to protect from light.

This medicine may be stored at temperatures not exceeding 25 °C for a maximum period of 3 months. In all cases, once initially removed from refrigerated storage, the medicine should be discarded after 3 months.

After opening, the medicine must be used immediately. Any unused solution must be discarded. Do not use this medicine if you notice visible signs of deterioration. Only clean and colourless solution free from particles or precipitates should be used.

Do not throw away any medicines via wastewater. 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 with Adrenaline contains

- The active substances are lidocaine hydrochloride and adrenaline.

Lidocaine 10 mg/ml (1% w/v) with Adrenaline (Epinephrine) 1:200 000:

Each ml of solution for injection contains lidocaine hydrochloride monohydrate equivalent to 10 mg of lidocaine hydrochloride and adrenaline (epinephrine) tartrate equivalent to 5 micrograms of adrenaline (epinephrine).

Each 10 ml ampoule contains lidocaine hydrochloride monohydrate equivalent to 100 mg of lidocaine hydrochloride and adrenaline (epinephrine) tartrate equivalent to 50 micrograms of adrenaline (epinephrine).

Lidocaine 20 mg/ml (2% w/v) with Adrenaline (Epinephrine) 1:200 000:

Each ml of solution for injection contains lidocaine hydrochloride monohydrate equivalent to 20 mg of lidocaine hydrochloride and adrenaline (epinephrine) tartrate equivalent to 5 micrograms of adrenaline (epinephrine).

Each 10 ml ampoule contains lidocaine hydrochloride monohydrate equivalent to 200 mg of lidocaine hydrochloride and adrenaline (epinephrine) tartrate equivalent to 50 micrograms of adrenaline (epinephrine).

- The other ingredients are sodium chloride, concentrated hydrochloride acid (for pH-adjustment), sodium hydroxide (for pH-adjustment), sodium metabisulfite (E223), water for injections (see section 2 “Lidocaine with Adrenaline contains sodium and sodium metabisulfite (E223)”).

What Lidocaine with Adrenaline looks like and contents of the pack

This medicine is a clear and colourless aqueous solution for injection (injection) practically free from particles. The solution is contained in a colourless glass ampoule filled with 10 ml. Each pack contains 10 ampoules.

Marketing Authorisation Holder

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Manufacturer

Delpharm Dijon
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