

Patient Information Leaflet

Lidocaine 1% with preservative Injection

Important information about your medicine

- ▶ Your doctor or nurse will give you the injection
- ▶ If this injection causes you any problems talk to your doctor, nurse or pharmacist
- ▶ Please tell your doctor or pharmacist, if you have any other medical conditions or have an allergy to any of the ingredients of this medicine
- ▶ Please tell your doctor or pharmacist, if you are taking any other medicines

- Read all of this leaflet carefully before you start using this medicine. In some circumstances this may not be possible and this leaflet will be kept in a safe place should you wish to read it.
- Keep this leaflet. You may need to read it again
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Where to find information in this leaflet

1. What Lidocaine 1% with preservative Injection is and what it is used for
2. Before you are given Lidocaine 1% with preservative Injection
3. How to use Lidocaine 1% with preservative Injection
4. Possible side effects
5. Storing Lidocaine 1% with preservative Injection
6. Further information

1. What Lidocaine 1% with preservative Injection is and what it is used for

Lidocaine 1% with preservative Injection is a local anaesthetic and is used to produce local anaesthesia (numb a specific area) and stop pain being felt in the area of the body where it is administered.

2. Before you are given Lidocaine 1% with preservative Injection

You should NOT be given Lidocaine 1% with preservative Injection if you:

- Are sensitive or allergic to Lidocaine Hydrochloride or any of the preservatives (methylhydroxybenzoate and propylhydroxybenzoate) or other ingredients in this injection. The preservatives are often known just as benzoates or hydroxyl-benzoates. (see also section

4. "Possible side effects" for further information)

Tell your doctor if you ever had an allergic or bad reaction, for example, skin rash or breathlessness, to any local anaesthetic medicines or to any preservatives.

- Have certain heart disorders. Tell your doctor if you have any heart problems particularly where your heart may pump blood less efficiently, may beat irregularly, or may beat more slowly.

Please tell your doctor or nurse before being given the injection if you:

- suffer from Porphyria - a disorder of the blood. Tell your doctor if you have any blood disorders.
- suffer from a heart or a breathing disorder.
- have kidney or liver disease.
- are feeling unwell or run down for any reason.
- suffer from epilepsy or have fits.
- have myasthenia gravis (a condition causing weakness of your muscles).
- are in shock.
- have a blood disorder or an imbalance in the constituents of your blood.
- have inflammation or infection in the area to be injected.

Using other medicines:

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important with the following medicines as they may interact with your Lidocaine 1% with preservative Injection:

- Acetazolamide (used to reduce pressure within the eye).
- Cimetidine (for stomach ulcer or heartburn).
- Dolasetron (used to prevent / treat nausea and vomiting).
- Quinupristin and dalfopristin (antibiotics)

- Beta-blockers, for example propranolol, (for angina, high blood pressure or other heart problems).
- Diuretics (water tablets).
- Anti-virals - medicines used to treat infections caused by viruses (e.g. HIV).
- Anti-arrhythmics - medicines used to regulate the rhythm of your heart.
- Anti-psychotics - medicines used to treat certain psychiatric conditions (e.g. Schizophrenia).
- Muscle relaxants, (e.g. Suxamethonium).

Pregnancy or breast feeding:

Please tell your doctor or nurse before being given this injection if you are pregnant or breast feeding. The doctor will then decide if the injection is suitable for you.

Driving and using machines:

Depending on where and how Lidocaine 1% with preservative Injection is used, it may affect your ability to drive or operate machinery. Ask your doctor about when it would be safe to drive or operate machines.

You should not drive or use machinery if you are affected by the administration of Lidocaine 1% with preservative Injection.

3. How to use Lidocaine 1% with preservative Injection

Your nurse or doctor will give you the injection.

Your doctor will decide the correct dosage for you and how and when the injection will be given.

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much, you must tell the person giving you the injection. Lidocaine 1% with preservative Injection is only intended to be given by injection under your skin (subcutaneously or SC).

4. Possible side effects

Like all medicines, Lidocaine 1% with preservative Injection can cause side effects, although not everybody gets them.

Allergic reactions:

- Allergic reactions to lidocaine hydrochloride are rare, but tell your doctor immediately if you get any difficulty with your breathing, a rash or itchy skin.
- The preservatives (see section 6. "Further information") used in this injection may cause allergic reactions (possibly delayed) and very rarely bronchospasm (your breathing may stop).

Nervous and psychiatric disorders:

- Dizziness or lightheadedness, drowsiness, tremor, confusion, your tongue going numb - sometimes these symptoms may indicate that you have been given too much lidocaine.
- Convulsions (seizures).

Eye disorders:

- Blurred or double vision.

Ear disorders:

- Tinnitus (a ringing in your ears).
- Hyperacusis (you are more sensitive to everyday sounds).

Heart disorders:

- Increased or decreased blood pressure.
- Slowing and stopping of your heart.
- Changes in the rhythm of your heart.

Breathing disorders:

- You may find it more difficult to breathe or your breathing may stop.

Gastrointestinal disorders:

- Nausea (feeling sick) and vomiting (being sick).

Skin disorders:

- Rash, itching and swelling of the face.

- Pain, inflammation or numbness at the site of injection after the effects of the injection should have worn off.

For patients going home before the numbness or loss of feeling caused by a local anaesthetic wears off:

- During the time that the injected area feels numb, serious injury can occur without your knowing about it. Be especially careful to avoid injury until the anaesthetic wears off or feeling returns to the area.

If you think this injection is causing you any problems, or you are at all worried, talk to your doctor, nurse or pharmacist.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine..

5. Storing Lidocaine 1% with preservative Injection

Your injection will be stored between 10°C and 25°C and protected from light. The nurse or doctor will check that the injection is not past its expiry date before giving you the injection.

6. Further information

What Lidocaine 1% with preservative Injection contains:

This injection contains the active ingredient lidocaine hydrochloride. This is the new name for lignocaine hydrochloride. The ingredient itself has not changed. Each 1 ml of solution contains 10 mg of lidocaine hydrochloride in a sterile solution for injection.

This injection contains the following inactive ingredients: Sodium chloride, water for injections and the preservatives methylhydroxybenzoate (E218) and propylhydroxybenzoate (E216).

What Lidocaine 1% with preservative Injection looks like and contents of the pack:

Lidocaine 1% with preservative Injection is a clear, colourless, sterile and isotonic solution in a 2 ml clear glass cartridge with a non-aspirated plunger and an aluminium crimping cap.

The marketing authorisation number of this medicine is: PL 01502/ 0070

Marketing Authorisation Holder:

hameln pharmaceuticals ltd

Gloucester

United Kingdom

Manufacturer:

Weimer Pharma

Rastatt

Germany

For any information about this medicine, please contact the Marketing Authorisation Holder

This leaflet was last approved February 2015