

Lidocaine Injection with Preservative 2%

Lidocaine Hydrochloride

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 because it contains important information for you.** 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, **ask your doctor, pharmacist or nurse.**
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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

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2. What you need to know before you use Lidocaine Injection with Preservative 2%
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1. What Lidocaine Injection with Preservative 2% is and what it is used for

Lidocaine Injection with Preservative 2% 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. What you need to know before you use Lidocaine Injection with Preservative 2%

Do NOT use Lidocaine Injection with Preservative 2%:

- 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**.
- if you 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.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Lidocaine Injection with Preservative 2%:

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

- if you have **inflammation** or **infection** in the **area** to be injected.

Other medicines and Lidocaine Injection with Preservative 2%:

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is especially important with the following medicines as they may interact with your Lidocaine Injection with Preservative 2%:

- **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**, e.g. 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. (e.g. Amiodarone, mexiletine)
- **Anti-psychotics** - medicines used to treat certain psychiatric conditions (e.g. Pimozide, sertindole)
- **Muscle relaxants**, (e.g. Suxamethonium) .

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 where and how Lidocaine Injection with Preservative 2% 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 Injection with Preservative 2%.

3. How to use Lidocaine Injection with Preservative 2%

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.

If you use more Lidocaine Injection with Preservative 2% than you should

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**, or you begin to experience **lightheadedness, numbness** of your tongue or a **ringing** in your ears you must tell the person giving you the injection **immediately**.

Lidocaine Injection with Preservative 2% is **only** intended to be given by injection under your **skin** (subcutaneously or SC).

4. Possible side effects

Like all medicines, Lidocaine Injection with Preservative 2% 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.

Blood disorders

- You may experience a **blueish discolouration** to your skin, a headache, breathlessness and fatigue as a result of abnormal amounts of methaemoglobin (a form of haemoglobin) in your blood

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. How to store Lidocaine Injection with Preservative 2%

Keep this medicine out of the sight and reach of children.

Your injection will be stored between 10°C and 25°C and protected from light.

Do not use this medicine after the expiry date which is stated on the label and carton after "Exp. date". The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Lidocaine Injection with Preservative 2% contains:

The active substance is lidocaine hydrochloride. In Lidocaine Injection with Preservative 2% each 1 ml of solution contains 20 mg of lidocaine hydrochloride in a sterile solution for injection.

The other ingredients are sodium chloride, water for injections and the preservatives methylhydroxybenzoate (E218) and propylhydroxybenzoate (E216).

What Lidocaine Injection with Preservative 2% looks like and contents of the pack:

Lidocaine Injection with Preservative 2% is a clear, colourless, sterile and isotonic solution in 20 and 50 ml clear glass vials. Not all vial sizes may be marketed.

The marketing authorisation number of this medicine is: PL 01502/ 0036

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

This leaflet was last revised November 2021.

44179/49/21