Package leaflet: Information for the patient

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Lidocaine Hydrochloride Injection 1% 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, 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

- 1. What Lidocaine Hydrochloride Injection 1% is and what it is used for
- 2. What you need to know before you use Lidocaine Hydrochloride Injection 1%
- 3. How to use Lidocaine Hydrochloride Injection 1%
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- What Lidocaine Hydrochloride Injection 1% is and what it is used for

Lidocaine Hydrochloride Injection 1% is a local anaesthetic. It 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.
- control fast or abnormal heart beats that you might experience after a heart attack.
- 2. What you need to know before you use Lidocaine Hydrochloride Injection 1%

Do NOT use Lidocaine Hydrochloride Injection 1%:

- if you are **allergic** to Lidocaine Hydrochloride or any of the other ingredients in this injection (listed in section 6). Tell your doctor if you ever had an allergic or bad reaction, for example, skin rash or breathlessness, to any local anaesthetic medicines.
- · 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.
- · if you suffer from a state of decreased blood volume (hypovolaemia)
- · if you suffer from Porphyria a disorder of the blood. Tell your doctor if you have any blood disorders.

preparation of this particular icine (i.e. hameln Lidocaine The medicine Hydrochloride Injection 1%) makes it unsuitable for use in the eye - therefore this medicine MUST NOT be used in the eye.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Lidocaine Hydrochloride Injection 1%:

- · 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

- Anti-psychotics medicines used to treat certain psychiatric conditions (e.g. Pimozide, Sertindole)
- Muscle relaxants, (e.g. Suxamethonium).
- Opioids strong relieving pain medicines (e.g. Fentanyl)
- oral HRT Oral contraceptives or (Hormone Replacement Therapy)

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 hydrochloride 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 Hydrochloride Injection 1%.

3. How to use Lidocaine Hydrochloride Injection 1%

This medicine (i.e. hameln Lidocaine Hydrochloride Injection 1%) MUST NOT be used in the eye.

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.

Lidocaine lf you use more Hydrochloride Injection 1% 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.

4. Possible side effects

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

Allergic reactions:

lidocaine Allergic reactions to hydrochloride are rare, but tell your doctor immediately if you get any difficulty with your breathing, a rash or itchy skin.

Nervous and psychiatric disorders:

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



Hydrochloride Injection 1%:

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 Lidocaine Hydrochloride your Injection 1%:

- · 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)
- Channel Blockers Calcium e.g. Verapamil, (for angina and high blood pressure).
- 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).

- Convulsions (seizures).

Eye disorders:

- Clouding of the cornea (the front part of the eye) has been reported when this medicine (i.e. hameln Lidocaine Hydrochloride Injection 1%) has been used in the eye.
- 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

may experience a You 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

After spinal injection of lidocaine, you should tell your doctor if you experience any of the following side effects:

- Pain or numbness in the back or lower legs.
- Difficulty in walking.
- · Problems with controlling your bladder or bowels.
- Feeling faint or light headed.
- Slow heart rate or pulse rate.

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 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.

How to store <u>Lidocaine</u> Hydrochloride Injection 1%

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

Your injection will be stored at less than 25°C and protected from light.

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

Contents of the pack and other 6. information

What Lidocaine Hydrochloride Injection 1% contains:

The active substance is lidocaine hydrochloride. In Lidocaine Hydrochloride Injection 1% each ml of solution contains 10 mg of lidocaine hydrochloride in a sterile solution for injection.

The other ingredients are hydrochloric acid, sodium hydroxide and water for injections.

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

Lidocaine Hydrochloride Injection 1% is a clear, colourless, solution for injection in a clear glass ampoule containing 2, 5, 10 or 20 ml. Not all ampoule sizes may be marketed.

The marketing authorisation number of this medicine is: PL 01502/0002R.

Marketing Authorisation Holder:

hameln pharma ltd



Nexus, Gloucester Business Park, Gloucester, GL3 4AG United Kingdom



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

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