

PATIENT INFORMATION LEAFLET




Read all of this leaflet carefully before you start taking this medicine.

- **Keep this leaflet. You may need to read it again.**
- **If you have 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.**

In this leaflet:

1. What your medicine is and what it is used for
2. Before you receive it
3. How it is administered
4. Possible side effects
5. Storing it

Lidocaine Injection with Preservative 2%



The active ingredient in this medicine is lidocaine hydrochloride. This is the new name for lignocaine hydrochloride. The ingredient itself has not changed.

This injection contains the active ingredient lidocaine hydrochloride 2%. Each ml contains 20 mg of lidocaine hydrochloride.

This injection also contains the following inactive ingredients:

Sodium chloride, methylhydroxybenzoate (E218), propylhydroxybenzoate (E216) and water for injections.

Holder of the Marketing Authorisation:

hameln pharmaceuticals ltd
Gloucester
United Kingdom

Manufacturer:

hameln pharmaceuticals gmbh
Langes Feld 13, 31789 Hameln
Germany

1. What your medicine is and what it is used for

Lidocaine Injection with Preservative 2% is a clear, colourless, sterile and isotonic solution supplied in 20 and 50 ml clear glass vials, only intended to be given by injection under your skin (subcutaneously or SC).

Lidocaine is a local anaesthetic of the amide group. When injected into the skin, it causes loss

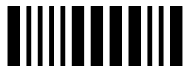
of feeling before or during surgery. Lidocaine allows doctors to sew up cuts in the skin and to undertake operations without any pain even though the patient is awake.

2. Before you receive your medicine

You should tell your doctor if:

- you think you are allergic to either lidocaine or the preservatives used in this injection. The preservatives are often known just as benzoates or hydroxy-benzoates. (See also section 4. Possible side effects for further information).
- you suffer from epilepsy or have fits
- you suffer from heart, lung or breathing disorders
- you have kidney or liver disease
- you suffer from myasthenia gravis (loss of muscle function and weakness)
- you are pregnant, likely to become pregnant or breast-feeding
- you have inflammation or infection in the area to be injected
- you are taking cimetidine (for stomach ulcer or heartburn) or beta-blockers, for example, propranolol (for angina, high blood pressure or other heart problems)





Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Driving and operating machinery: Depending on where and how lidocaine 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.

3. How your medicine is administered

The dose of a local anaesthetic will be different for different patients. Your healthcare professional will decide on the right amount for you, depending on:

Your age; your general physical condition; the reason the local anaesthetic is being given and other medicines you are taking or will receive before or after the local anaesthetic is given.



Adults: As a guide, 10 ml (equivalent to 200 mg) of Lidocaine Injection with Preservative 2% is the usual maximum dose. Your doctor will decide on the most appropriate dose for you. A smaller dose may be used if you are elderly or weak.

Children: A smaller dose is usually used for children depending on their age, physical condition and the procedure to be performed.

4. Possible side effects

Like all medicines, Lidocaine Injection with Preservative 2% can have side effects:

Lidocaine is generally well tolerated, but along with its needed effects, all medicine can cause unwanted effects. Lidocaine may occasionally cause the following side effects:

- pain, inflammation or numbness at the site of injection after the effects of the injection should have worn off
- nervousness
- tremor
- blurred or double vision
- dizziness or drowsiness
- convulsions (seizures)
- nausea or vomiting
- breathing problems
- slowed heart beat or low blood pressure

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.

Methylhydroxybenzoate (E218) and propylhydroxybenzoate (E216) may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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.

5. Storing your medicine

Your doctor will store the vials in the outer carton in order to protect from light, between 10°C and 25°C and out of reach and sight of children

6. Use by date

Your doctor will not use the drug after the expiry date shown on the vial and carton.

This leaflet was last updated on July 13th, 2004.

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