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Patient Information Leaflet: Lidocaine Hydrochloride Injection BP Minijet®, 1% and 2% w/v. Solution for Injection. Lidocaine Hydrochloride.

Lidocaine Hydrochloride Injection BP Minijet®, 1% and 2% w/v. Solution for Injection. Lidocaine Hydrochloride.

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or nurse
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- In this leaflet, Lidocaine Hydrochloride Injection BP Minijet will be called Lidocaine Injection.

In this leaflet:

1. What Lidocaine Injection is for
2. Before you are given Lidocaine Injection
3. How Lidocaine Injection will be given to you
4. Possible side effects
5. How to store Lidocaine Injection
6. Further information

1. What Lidocaine Injection is for

Lidocaine Injection belongs to a group of medicines called local anaesthetics.

Local anaesthetics work by numbing the area of the body that they are injected into which stops pain being felt.

Lidocaine Injection is used to stop pain being felt during medical investigations, operations or in labour.

Lidocaine Injection can also be used to treat heartbeat disturbances, especially after heart attacks or in heart surgery.

2. Before you are given Lidocaine Injection

You should not be given Lidocaine Injection if:

- You are allergic to lidocaine or other local anaesthetics
- You are allergic to any of the other ingredients of Lidocaine Injection (listed in section 6)
- You have acute porphyria (a blood disorder in which excessive blood pigment, porphyrin is excreted in the urine and you are extremely sensitive to light).
- You suffer from a slow or irregular heartbeat or heart block
- You suffer from Stokes-Adams syndrome or attacks of temporary loss of consciousness

If any of the above applies to you, you should not be given Lidocaine Injection, talk to your doctor or nurse.

Check with your doctor or dentist before you are given Lidocaine Injection if:

- You have epilepsy
- You have liver disease
- You have any heart problems
- You have severe kidney disease
- You suffer from any lung disorders
- You have any blood disorders (particularly low blood volume, low oxygen or potassium levels)
- You have severe breathing difficulties
- You are having an epidural injection into your spine (e.g. clonidine or adrenaline)
- You are going to have a general anaesthetic that will involve the use of suxamethonium or cistracurium
- You suffer from loss of blood circulation or less oxygen in the tissue
- You suffer from high levels of potassium
- You are suffering from shock. This is an emergency condition where there is not enough oxygen reaching all parts of the body. This type of shock can cause many organs to stop

working properly.

Tell your doctor or dentist if you are taking any of the following medicines:

- Any medicines for a heart condition (e.g. kinidine, disopyramide, amiodarone, bretylium, sotalol, dofetilide, metoprolol and nadolol)
- Medicines for high blood pressure (e.g. propranolol)
- Medicines for a stomach ulcer (e.g. cimetidine)
- Medicines for epilepsy (e.g. phenytoin), infections (e.g. erythromycin), depression (e.g. fluvoxamine) or glaucoma (e.g. acetazolamide)
- Oral contraception or oral HRT
- Suxamethonium or cistracurium used as muscle relaxants during a general anaesthetic
- You are having Lidocaine as an epidural (injection into the spine) with clonidine and/or adrenaline or morphine
- Medicines to increase the rate of urination (e.g. loop diuretics or thiazides)
- You are taking any other medicine, including medicines obtained without

a prescription.

If any of the above applies to you talk to your doctor or nurse.

Pregnancy and breast-feeding

If you are pregnant, in labour or breastfeeding, Lidocaine Injection will only be given to you if your doctor considers that the benefit of treatment outweighs the risk to the developing baby or new-born baby.

Lidocaine is excreted in breast milk, so if you are breastfeeding, your doctor or nurse will observe your baby for any side effects.

Warnings about the ingredients in Lidocaine injection

This medicinal product contains less than 1 mmol sodium per dose, in other words it is essentially 'sodium-free'.

3. How Lidocaine Injection will be given to you

Important:
Lidocaine Injection will be given to you by a doctor, or nurse in hospital or a dentist. Your doctor or dentist will choose the dose that is right for you.

- Lidocaine Injection is injected into the area that needs to be numbed

- You will be given the lowest possible dose.
- The exact dose you will be given depends on the area to be numbed, the way the injection is being given and how you respond to it.
- Your doctor or nurse may put a tight band (tourniquet) around your limb if you require what is called intravenous regional anaesthesia (or Bier's block). The band is kept in place for at least 20 minutes after injection. This keeps the lidocaine in the area it is needed.

Adults

- When this medicine is given as a local anaesthetic the maximum dose is 3mg per kg of body weight or 200mg.
- When given as a continues pain relief (often used in labour) the maximum dose will be given at least 90 minutes apart
- When given for heart problems the usual dose is 50-100mg injected into a vein. This can be repeated after 5 minutes but no more than 300mg should be given in one hour.

Elderly

- Your doctor may reduce the dose depending on your age and physical condition.

Children

- When this medicine is given as a local anaesthetic the usual dose is up to a maximum of 3mg per kg of body weight
- When given for heart problems the usual dose is 0.8-1mg for every kg of body weight injected into a vein. This can be repeated up to 3-5mg/kg. This may be followed by 10-50 micrograms per kg of body weight per minute given as a drip.

Medical check-ups

- Your doctor will monitor your heart whilst giving you Lidocaine Injection as an injection into a vein.
- Your baby's heart rate will be monitored if you are given Lidocaine injections around your cervix during labour.
- Your blood pressure will be monitored if you have Lidocaine injected into your spine or around your cervix.

This is to make sure that your medicine is working properly and that the dose you are given is right for you.

If you think you may be given more Lidocaine Injection than you should

As this medicine will be given to you by a doctor or nurse, it is unlikely that you will be given too little or too much. However, tell your doctor or nurse if you have any concerns.

The effects of an overdose may include fits, chest pains and unconsciousness.

If you have any further questions about the use of this medicine, ask your doctor or nurse.

4. Possible side effects

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

Seek immediate medical help if you have any of the following symptoms:

Allergic reactions causing

- Swelling of hands, feet, lips, mouth, tongue or throat
- Difficulties breathing
- Itchy skin rash
- Diarrhoea and stomach pains
- Collapse.

The other side effects are:

Effects on the lungs

- breathing problems or you may stop breathing

Effects on the heart and circulation:

- irregular heart beat
- a sudden loss of blood flow due to heart or vessel factors and a very slow heart rate which may lead to a heart attack.
- problems with the electrical system of the heart and reduced function of your heart
- low blood pressure

Effects on the nervous system

- unconsciousness
- fits
- twitching or tremors
- feeling sick or being sick
- dizziness or light headedness
- drowsiness
- a feeling of apprehension, nervousness or extreme happiness
- a feeling of confusion or being unable to distinguish between reality and your imagination
- headache
- sensations of heat, cold or numbness
- pins and needles

Other effects

- blurred or double vision
- uncontrolled movement of the eyes

- ringing in the ears
- temporary pain or discomfort in the buttocks or legs
- a blood disorder where excessive haemoglobin in the blood is converted to another chemical that cannot deliver oxygen to tissues.

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:

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie.

United Kingdom

Yellow Card Scheme
Website: 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

Keep out of the reach and sight of children.

Do not use Lidocaine Injection after the

expiry date on the carton and vial label. The expiry date refers to the last day of that month.

Do not store above 25°C.

For single use only. Discard any unused portion.

Do not use Lidocaine Injection if there is any colour to the solution or if there are any particles in the vial.

Your doctor, nurse or dentist will make sure your medicine is correctly stored and disposed of.

6. Further information

What Lidocaine Injection contains

The active substance is lidocaine hydrochloride. There are two strengths of Lidocaine Injection:

- The 10 mg/ml (1 % w/v) strength contains 100 mg in 10 ml of solution
- The 20 mg/ml (2 % w/v) strength contains 100mg in 5 ml of solution.

The other ingredients are hydrochloric acid and sodium hydroxide (for pH adjustment), sodium chloride and water for injections.

What Lidocaine Injection looks like

Lidocaine Injection is a clear, colourless sterile solution for injection in a clear glass container called a vial.

Marketing Authorisation Holder

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If this leaflet is difficult to see or read or you would like it in a different format, please contact:

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