Package leaflet: Information for the user

Lidocaine Hydrochloride 2% w/v Solution for Injection
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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lidocaine Injection is and what it is used for
Lidocaine Hydrochloride is a local anaesthetic. It produces loss of feeling or sensation confined to one part of the body (local anaesthesia). Lidocaine belongs to a group of medicines called amide-type local anaesthetics.

Lidocaine Injection may be used to produce local anaesthesia by injection of the solution into or around a peripheral nerve or network of nerves, in children and adults. It may also be used in adults to relieve pain by administering the solution into the epidural space, which is close to the spinal cord, or into a vein in a limb that has been isolated from the circulation by means of a tourniquet. The dosage should be adjusted according to the response of the patient and the site of administration and with precautions in children and elderly.

2. What you need to know before you take Lidocaine Injection

Do not use Lidocaine Injection if you:

- Are allergic to lidocaine or to any other amide-type of local anaesthetic or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or nurse before using Lidocaine Injection

- you are pregnant, likely to be pregnant, or breast feeding
- you suffer from epilepsy, heart disease, breathing problems or a disease of the liver or kidneys
- you have either inflammation or an infection of the skin with pus at or near the site to be injected

Other medicines and Lidocaine Injection

Tell your doctor or pharmacist if you 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 Injection:

- beta-adrenoreceptor blocking agents (e.g. propranolol**)** - for the treatment of high blood pressure, angina (chest pain) or heart attacks
- cimetidine - to treat hyperacidity, stomach & duodenal ulcers
- acetazolamide - to treat glaucoma (increased pressure in the eye)
- thiazides & loop diuretics - medicines to increase your urine output
- antiarrhythmics - medicines to treat abnormal heart rhythms
- quinupristin/dalfopristin - an antibiotic
- suxamethonium - a muscle relaxant

This medicinal product contains less than 1mmol Sodium (23mg) per dose, ie. essentially 'Sodium-free'.

Pregnancy, breast-feeding and fertility

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 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 2% w/v Injection.

3. How to take Lidocaine Injection

Your nurse or doctor will give you the injection

The site of injection will depend on the area to be anaesthetised. Your physician will decide on the most suitable dosage and this will depend on the site of injection, the procedure used and your response to the injection. The maximum dose is 3mg per kg of bodyweight or 200mg, whichever is the lower. Children, elderly patients or patients in a weak condition require smaller doses, depending on their age and physical condition.

In adults and children it can be used by administering near peripheral nerves (infiltration by injection). It can also be used in adults by administering into the veins in a limb that has been isolated from the circulation by means of a tourniquet or administering into epidural space near spinal cord. Lidocaine injection should not be administered in veins or epidural space for local anesthesia in children.

What to do in case of a missed dose or an overdose:

If you think that you may have missed a dose, or that you may have been given too much of this injection, tell your physician.

4. Possible side effects

Lidocaine is generally well tolerated. Like other amide-type local anaesthetics, lidocaine may occasionally cause unwanted effects. Only in rare cases have amide-type local anaesthetics been associated with allergic reactions (such as a skin rash, shortness of breath or fall in blood pressure). Serious side-effects are rare, but may occur in case of an overdosage or if the solution is rapidly absorbed from the injection site or if it is accidentally injected into a blood vessel. In these circumstances symptoms such as nervousness, dizziness, buzzing in the ears, blurred vision, shakiness, twitching, drowsiness, feeling breathless or feeling faint

may occur. Lidocaine may result in abnormal amount of methemoglobin (a form of hemoglobin in blood) which may cause bluish discoloration of skin, headache, shortness of breath, malaise and fatigue.

Other side effects include:
• changes in the rhythm and speed of the heart.
• pain at the injection site, or numbness or loss of power after the effects of the injection should have worn off
• difficulty in passing water
• feeling sick or being sick (nausea or vomiting)
• drowsiness, dizziness, mood changes,
• vision difficulties
• convulsions
• low blood pressure

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 controlling your bladder or bowels
• faintness of light headed feeling
• slow heart or pulse rate

If you experience any of these side-effects, or if you notice any unwanted effects that are not mentioned here, tell your physician.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.Website: www.hpra.ie e-mail: medsafety@hpra.ie.By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lidocaine Injection

Keep Lidocaine Injection out of the sight and reach of children.

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

Do not store above 25°C. Keep the ampoules in the outer carton in order to protect from light.

This product should be used immediately after opening.

If only part used, discard the remaining solution.

For single use only.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Lidocaine Injection contains

The active ingredient in this medicine is Lidocaine. This is the new name for Lignocaine. The active ingredient itself has not changed Lidocaine Injection is a clear, colourless, sterile solution for injection containing the active ingredient Lidocaine Hydrochloride.

Each 2ml of solution contains 40mg (20mg in 1ml) lidocaine hydrochloride.
Each 5ml of solution contains 100mg (20mg in 1ml) lidocaine hydrochloride.

Inactive ingredients:

Sodium Chloride, Sodium Hydroxide (as a 10% w/v solution) or dilute Hydrochloric Acid in Water for Injections.

Pack Sizes:
Each carton contains 10 glass ampoules.
Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer:

Mercury Pharmaceuticals (Ireland) Ltd
4045, Kingswood Road, City West Business Park, Co Dublin, Ireland
.
Product Authorisation Number:
2% w/v 2ml: PA 73/112/6
2% w/v 5ml: PA 73/112/6

Name of the Manufacturer:
B. Braun Melsungen AG,
Mistelweg 2, 12357, Berlin, Germany.

This leaflet was last revised in April 2016.

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What is in this leaflet

1. What Lidocaine Injection is and what it is used for

Lidocaine Hydrochloride is a local anaesthetic. It produces loss of feeling or sensation confined to one part of the body (local anaesthesia). Lidocaine belongs to a group of medicines called amide-type local anaesthetics.

Lidocaine Injection BP may be used to produce local anaesthesia by injection of the solution into or around a peripheral nerve or network of nerves, in children and adults. It may also be used in adults to relieve pain by administering the solution into the epidural space, which is close to the spinal cord, or into a vein in a limb that has been isolated from the circulation by means of a tourniquet. The dosage should be adjusted according to the response of the patient and the site of administration and with precautions in children and elderly.

2. What you need to know before you take Lidocaine Injection

Do not use Lidocaine Injection if you:

- Are allergic to lidocaine or to any other amide-type of local anaesthetic or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or nurse before using Lidocaine Injection

- you are pregnant, likely to be pregnant, or breast feeding
- you suffer from epilepsy, heart disease, breathing problems or a disease of the liver or kidneys
- you have either inflammation or an infection of the skin with pus at or near the site to be injected

Other medicines and Lidocaine Injection

Tell your doctor or pharmacist if you 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 Injection:

- beta-adrenoreceptor blocking agents (e.g. propranolol) - for the treatment of high blood pressure, angina (chest pain) or heart attacks
- cimetidine - to treat hyperacidity,stomach & duodenal ulcers
- acetazolamide - to treat glaucoma (increased pressure in the eye)
- thiazides & loop diuretics - medicines to increase your urine output
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- quinupristin/dalfopristin - an antibiotic
- suxamethonium - a muscle relaxant

This medicinal product contains less than 1mmol Sodium (23mg) per dose, ie. essentially 'Sodium-free'.

Pregnancy, breast-feeding and fertility

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 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 2% w/v Injection.

3. How to take Lidocaine Injection

Your nurse or doctor will give you the injection.

The site of injection will depend on the area to be anaesthetised. Your physician will decide on the most suitable dosage and this will depend on the site of injection, the procedure used and your response to the injection. The maximum dose is 3mg per kg of bodyweight or 200mg, whichever is the lower. Children, elderly patients or patients in a weak condition require smaller doses, depending on their age and physical condition.
In adults and children it can be used by administering near peripheral nerves (infiltration by injection). It can also be used in adults by administering into the veins in a limb that has been isolated from the circulation by means of a tourniquet or administering into epidural space near spinal cord. Lidocaine injection should not be administered in veins or epidural space for local anesthesia in children.

What to do in case of a missed dose or an overdose:

If you think that you may have missed a dose, or that you may have been given too much of this injection, tell your physician.

4. Possible side effects

Lidocaine is generally well tolerated. Like other amide-type local anaesthetics, lidocaine may occasionally cause unwanted effects. Only in rare cases have amide-type local anaesthetics been associated with allergic reactions (such as a skin rash, shortness of breath or fall in blood pressure). Serious side-effects are rare, but may occur in case of an overdosage or if the solution is rapidly absorbed from the injection site or if it is accidentally injected into a blood vessel. In these circumstances symptoms such as nervousness, dizziness,

buzzing in the ears, blurred vision, shakiness, twitching, drowsiness, feeling breathless or feeling faint may occur. Lidocaine may result in abnormal amount of methemoglobin (a form of hemoglobin in blood) which may cause bluish discoloration of skin, headache, shortness of breath, malaise and fatigue.

Other side effects include:
• changes in the rhythm and speed of the heart.
• pain at the injection site, or numbness or loss of power after the effects of the injection should have worn off
• difficulty in passing water
• feeling sick or being sick (nausea or vomiting)
• drowsiness, dizziness, mood changes,
• vision difficulties
• convulsions
• low blood pressure

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 controlling your bladder or bowels
• faintness of light headed feeling
• slow heart or pulse rate

If you experience any of these side-effects, or if you notice any unwanted effects that are not mentioned here, tell your physician.

Reporting of side effects

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5. How to store Lidocaine Injection

Keep Lidocaine Injection out of the sight and reach of children.
Do not use Lidocaine Injection after the expiry date which is stated on the carton and ampoule label after Exp. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the ampoules in the outer carton in order to protect from light.

This product should be used immediately after opening.

If only part used, discard the remaining solution.

For single use only.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Lidocaine Injection contains

The active ingredient in this medicine is Lidocaine. This is the new name for Lignocaine. The active ingredient itself has not changed Lidocaine Injection is a clear, colourless, sterile solution for injection containing the active ingredient Lidocaine Hydrochloride.

Each 20ml of solution contains 400mg (20mg/ml) lidocaine hydrochloride.

Inactive ingredients:

Sodium Chloride, Sodium Hydroxide (as a 10% w/v solution) or dilute Hydrochloric Acid in Water for Injections.

Pack Sizes:
Each carton contains 10 glass ampoules.
Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer
Mercury Pharmaceuticals (Ireland) Ltd
4045, Kingswood Road, City West Business Park, Co Dublin, Ireland
.
Product Authorisation Number:
2% w/v 20ml: PA 73/112/6

Name of the Manufacturer:
B. Braun Melsungen AG,
Mistelweg 2, 12357, Berlin, Germany.

This leaflet was last revised in April 2016.