PATIENT INFORMATION LEAFLET

0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion

- ***Active substance:*** Each 100 ml solution contains 0.4 g lidocaine hydrochloride.
- ***Excipients:*** Dextrose anhydrous, water for injection

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION 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. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use* ***higher or lower*** *dose other than your recommended dose.*

In this leaflet:

headlines are included.

1. What 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion is and what it is used for

0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion is a solution used in the treatment of disorders in the heart rhythm.

0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion Presented in PP bags of 250 and 500 milliliters. There are two forms with and without set.

Lidocaine hydrochloride in the product reduces the excitability of the heart. In addition, it is given as an intravenous infusion in order to control the irregular activity (arrhythmia) in the heart in the period following cardiac surgery and heart attack. Also, digoxin (a medicine used to treat heart disorders) is used in patients with general anesthesia who may have an overdose and risk of heartbeat irregularity.

2. What you need to know before you use 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion

DO NOT USE 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion under the following circumstances

If you experienced any alergic reactions when you take any medicine which contain same active substance or excipients with 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion, which means if you had suddenly stopped breathing, wheezing, skin rashes, itching or swelling in your body, if you are allergic to corn products, if you are not sure whether you are allergic, consult your doctor.

- When blood volume drops (hypovolemia).
- If you have ever had an allergy to lidocaine or a local anesthetic drug like lidocaine (such as prilocaine, mepivacaine, bupivacaine).
- Decreased heart function (heart block).
- Heart conduction disorders (when there is a problem with the transmission of electrical signals in your heart).
- If your heart rate is too slow (bradycardia).
- In case of insufficient blood circulation to the heart (cardiac decomposition).
- High blood pressure (hypertension).
- Strokes-Adams Syndrome (sudden fainting).

USE 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion with CAUTION

If,
- Your epilepsy
- If you have heart failure,
- If you have breathing problems,
- If you have liver damage,
- If you have Myasthenia gravis (no muscle strength)
- If you have a circulatory disorder,
- If you have kidney problems,
- If you have low blood pressure,
- If you are using a pacemaker,
- If you are pregnant,
- If you are breastfeeding,

- If you are using other medicines for irregular heartbeat or if you are using an over-the-counter medication for any purpose, this medication will be administered with caution to you.

It is recommended that the tubes (sets) used when applying this medicine are changed every 24 hours.
Also, it should only be used if the bag is intact and leak-free, if the solution in it is clear.

Using 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion with food and beverages
0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion is an intravenous drug; There is no interaction with foods and beverages in terms of application.

Pregnancy
Please consult your physician or pharmacist before taking the drug.

If you are pregnant, think that you are pregnant or plan to become pregnant, please consult your doctor.
You should not use 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion if you are pregnant. Use 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion under strict supervision of a doctor.

If you realize that you are pregnant during your treatment, immediately consult your physician or pharmacist.

Breast feeding
Please consult your physician or pharmacist before taking the drug.

If you are breastfeeding your baby, notify this to your doctor. Your doctor will decide whether you will be treated with 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion.

Ability to drive and use machines
Not applicable.

Important information regarding some of the excipients contained in 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion
If you are not sensitive to the excipients contained in the 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion, a negative effect due to these substances is not expected.

It contains 12.5 g of glucose (sugar) per 250 ml and 25 g of 500 ml. This should be considered in patients with diabetes mellitus (diabetes).

Use in combination with other drugs
Please inform your doctor if you are using the following medicines or if you have recently used them:

• Beta-adrenergic blockers - a group of drugs used for heart arrhythmias.
Cimetidine - a drug used in reflux and peptic ulcer.
• Phenytoin- an antiepileptic drug.
• Fluvoxamine - an antidepressant used to treat anxiety disorder (social phobia) or obsessive - compulsive disorder.
• Suksametonium: muscle relaxant.
• Nitrous oxide: an anesthetic agent.

If you are currently taking or recently took any prescribed or over-the-counter drugs, please inform your physician or pharmacist.

3. How to use 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion

Instructions regarding correct use and dosage/administration frequency:
0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion will be administered to you by a healthcare professional in a hospital.
Application dosage and speed varies according to your needs. Your doctor will decide the right dosage for you.
Following the loading dose, infusions containing lidocaine are administered at a rate of 1-4 mg/min for 12-48 hours.

Method of administration:
It is used through a plastic tube (set) suitable for your veins.

Various age groups:
Use in children:
In children, the dose is usually reduced. Depending on the ECG changes, the required dose will be adjusted by the doctor.

Use in elderly:
In the elderly, the dose is usually reduced. Depending on the ECG changes, the required dose will be adjusted by the doctor.

Special cases:
Renal failure:
If you have kidney dysfunction, your doctor will adjust the dose of your medicine.

Hepatic failure:
Karaciğer yetmezliğiniz var ise doktorunuz ilacınızın dozunu ayarlayacaktır.

If you are under the impression that the effect 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion is too strong or weak, consult your physician or pharmacist.

If you have taken more 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion than you should have:
It is not possible to use 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion more than applied to you. If you think you have overdosed, look for the symptoms and side effects mentioned in this leaflet. If you have any of these symptoms, tell your doctor right away.

If you forget to take 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion:
Do not double-dose to make up for forgotten doses.

Possible effects once 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion treatment is concluded:
Not applicable.

4. Possible side effects
Like all medicines, 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion may cause side effects in patients sensitive to its ingredients.

The frequency of side effects is classified into the following categories:

Very common: in more than 1 in 10 patients
Common : in more than 1 in 100 patients, but less than 1 in 10 patients
Uncommon : in more than 1 in 1,000 patients, but less than 1 in 100 patients
Rare : in more than 1 in 10,000 patients, but less than 1 in 1,000 patients
Very rare : in less than 1 in 10,000 patients, including isolated reports

If any of the following reactions happen, stop taking 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion and tell your doctor immediately or contact the casualty department at your nearest hospital:
- Sudden stop of the heartbeat (cardiac arrest)
- slowing or decreasing heart activity (myocardial depression)
Swelling (especially on the lips, face, eyelid, tongue, throat, hands, ankles and feet)
- Feeling breathless

These are all very serious side effects.

Since the solution for infusion will be administered to you by a healthcare professional, these symptoms will be monitored and if any of these serious side effects occur, treatment will be started immediately and treatment will be started.

All of these very serious side effects are very rare.

In addition, difficulty in breathing, dizziness and coma may be observed during this solution application.

All medicines infrequently may cause an allergic reaction.

If you notice any of the following side effects, tell your doctor immediately or contact the nearest emergency room:

Rare:

- Urticaria,
- Edema,
- Hypersensitivity (allergic reactions),
- Skin lesions (bruised area).

Unknown:

- Stretching
- Fainting feeling, fatigue,
- Excitement, euphoria (feeling of happiness),
- Tension, irritability, anxiety,
- Dizziness,
- Tinnitus,
- Flickering, blurred or double vision,
- Tongue and perioral (mouth circumference of the face) region numbness,
- Tremor (chills),
- Drowsiness,
- Coma,
- Feeling of heat or cold or numbness,
- Loss of consciousness, disorientation (disorientation), paresthesia (tingling, numbness),
- Difficulty swallowing,
- Speaking prolonged,
- Enlargement of the veins (peripheral vasodilation),
- High blood pressure (hypertension),
- Low blood pressure (hypotension),

- Slow heartbeat (bradycardia), irregular activity (arrhythmia) in the heart chambers, ventricular tachycardia/ventricular fibrillation (heart rhythm disturbances), cardiac arrest (cardiac arrest),
- Respiratory distress-difficulty, respiratory depression or cessation,
- Nausea, vomiting,
- Muscle twitching,
- Methemoglobinemia (condition that results in insufficient oxygen supply to the tissues),
- Convulsions (seizures), psychosis (a person's disconnection from reality).

These are all serious side effects. You may need urgent medical attention.

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

5. How to store 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion

Keep 0.4% LİDODEKS in 5% Dextrose Solution for I.V. Infusion out of the sight and reach of children, and in its original package.

Store at temperature below 25°C and in its original package.

For single use only.
Partly used solutions should not be kept and must be discarded in accordance with the local regulations.
Each bag contains expiry date information. If this date is expired, this product will not be administred to you.
Use in accordance with the expiry date.

Marketing Authorization Holder and Manufacturing Site:

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This patient information leaflet was approved on 05.08.2016.

THE FOLLOWING INFORMATION IS FOR THE HEALTH PERSONNEL WHO WILL APPLY THIS MEDICINE

This medicinal product is intended for intravenous administration only with sterile devices and sets. It should only be administered aseptically via intravenous infusion.

It is disposable. Partially used solutions should not be stored; It should be disposed of in accordance with the medical waste procedures of the health institution where intravenous administration is performed.

Parenteral drugs should be visually checked before use; only clear, particle-free and intact packaging products should be used.

Do not remove any protective covers until just before use; Start applying immediately after removing the protector. The protective outer sheath protects the product from evaporation by evaporating. The inner bag keeps the product sterile.

Caution: In order to prevent an air embolism that may occur due to residual air in the bag, serial connections should not be made with other infusion fluids.

To open:

• Remove the outer protector just before use. The protector is torn open and the bag is exposed. Start application immediately after removing the protector.

• Some opacity may be seen in the bag depending on the sterilization process. This is normal, it does not affect the quality and reliability of the solution. Opacity will gradually disappear.

• Check that the bag is intact after removing it from its protective packaging. The product should not be used if leakage is found; sterility may be impaired.

Application preparations:

1. Hang the bag.

2. Remove the protective cap on the application tip.

3. Attach the sprinkler of the application set tightly to the application tip and attach the application set to the bag.

4. The instructions for use of the set should be followed to apply the solution to the patient.

Adding additional medication:

Caution: As with all parenteral solutions, all substances to be added to the product must be compatible with the product. If additions will be made to the product, compatibility should be checked in the final mixture before applying to the patient.

Adding medication before application:

1. The drug delivery tip of the bag is disinfected.

2. The drug to be added is added to the bag with a 19-22 gauge needle with a syringe.

3. The solution and the medication added are thoroughly mixed. In dense drugs such as potassium chloride, the application exit of the bag is tapped while in the up position, allowing the drug to mix completely with the solution.

Caution: Bags with additional medication should not be stored.

Adding medication during application

1. The clamp of the set is closed.

2. The drug delivery tip is disinfected.

3. The drug to be added is applied into the bag with a 19-22 gauge needle with a syringe.

4. The solution is removed from the rack and turned over.

5. While in this position, the application exit and injection inlet of the bag is tapped gently to mix the solution and additional drug.

6. By bringing the bag back to its original position, the clamp is opened and the application is continued.