

PRODUCT MONOGRAPH

**2% Lidocaine Hydrochloride Injection USP**  
20 mg/mL

**0.4 % Lidocaine Hydrochloride and 5% Dextrose Injection USP**  
Lidocaine Hydrochloride and Dextrose Injection USP  
Lidocaine Hydrochloride (4 mg/mL) and Dextrose (50 mg/mL)

Antiarrhythmic Agent

Hospira Healthcare Corporation  
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H4S 0A9

Date of Preparation:  
October 19, 2015

Control No.: 187849

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**ACTION**

The mode of action of the antiarrhythmic effect of lidocaine appears to be similar to that of procaine, procainamide and quinidine. Ventricular excitability is depressed and the stimulation threshold of the ventricle is increased during diastole. The sinoatrial node is, however, unaffected. Lidocaine in recommended doses does not produce a significant decrease in arterial pressure nor in cardiac contractile force. In large doses, lidocaine hydrochloride may produce circulatory depression but the magnitude of the changes is less than that found with comparable doses of procainamide. Neither drug appreciably affects the duration of the absolute refractory period.

The onset of action following a single intravenous injection varies from 45 to 90 seconds and duration of action is 10 to 20 minutes. Lidocaine plasma levels have been correlated with clinical effectiveness. The therapeutic range is 1.2 to 6 mcg/mL. Plasma drug concentration higher than 5 to 6 mcg/mL increases the risk of toxicity.

## **INDICATIONS AND CLINICAL USES**

Intravenous administration of lidocaine hydrochloride is indicated in the treatment of ventricular tachycardia and premature ventricular beats of life-threatening nature, which may occur during acute myocardial infarction, digitalis toxicity or other cardiac diseases.

2% Lidocaine Hydrochloride Injections USP is designed for use only as direct intravenous injection.

0.4% Lidocaine Hydrochloride and 5% Dextrose Injection USP is designed for use only as continuous intravenous infusion when fluid restriction is desirable.

Constant electrocardiographic and blood pressure monitoring are essential.

## **CONTRAINDICATIONS**

Lidocaine is contraindicated in patients with:

1. hypersensitivity to local anesthetic of the amide type;
2. Stokes-Adams' Syndrome or severe degrees of sinoatrial, atrio-ventricular or intraventricular block;
3. advanced hepatic disease.

Dextrose solutions without electrolytes should not be administered simultaneously with blood through the same infusion set because of the possibility that pseudoagglutination of red cells may occur.

**NOTE:** The safety of lidocaine hydrochloride intravenous injection in children has not been established.

## **WARNINGS**

1. Constant ECG monitoring is essential for the proper administration of lidocaine **intravenously**. Signs of excessive depression of cardiac conductivity, such as prolongation of PR interval and QRS complex, and the appearance of aggravation of arrhythmias, should be followed by prompt cessation of the intravenous injection. Lidocaine hydrochloride Injection must be used in the treatment of cardiac arrhythmias under the constant supervision of a physician, with meticulous regulation of the rate of injection.

2. It is mandatory to have emergency resuscitative equipment and drugs immediately available to manage possible adverse reactions involving the cardiovascular, respiratory, or central nervous systems.
3. **Usage in Pregnancy:** Safety of lidocaine with respect to the development of the human fetus has not been adequately established. Therefore, the risk of benefit ratio should be determined when the use of lidocaine in early pregnancy is considered.
4. **Continuous Infusion:** Excess administration of potassium-free solutions may result in significant hypokalemia.

The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolytes concentrations, overhydration, congested states or pulmonary edema.

As the dosage of dilute solutions of lidocaine must be titrated to individual patient response, additive medications should not be delivered via this solution.

### **PRECAUTIONS**

- a) In patients with heart-block and bradycardia, severe digitalis intoxication and severe myocardial disease, any cardiac depressant should be used with caution (see **CONTRAINDICATIONS** and **WARNINGS**).
- b) Patients with congestive heart failure, shock, liver disease and patients over 70 years of age require smaller doses of lidocaine since the drug may accumulate in these patients and result in toxic manifestations.
- c) In unconscious patients, circulatory collapse should be watched for, since CNS effects may not be apparent as an initial manifestation of toxicity.
- d) The intravenous administration of lidocaine hydrochloride may sometimes be accompanied by a hypotensive response and, in overdosage, this could be precipitous. For this reason, the intravenous dose should not exceed 100 mg in a single injection, and no more than 200 to 300 mg should be given during a one-hour period (see **DOSAGE AND ADMINISTRATION**).
- e) Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.
- f) Solutions containing dextrose should be used with caution in patients with known

subclinical or overt diabetes mellitus.

- g) Do not administer unless solution is clear and container is undamaged. Discard unused portion.

### **DRUG INTERACTIONS**

Lidocaine hydrochloride should be used with caution in patients with digitalis toxicity accompanied by atrioventricular block. Concomitant use of beta-blocking agents (i.e., propranolol) or cimetidine may reduce hepatic blood flow and thereby reduce lidocaine hydrochloride clearance. The concomitant use of these two agents may cause an increased incidence of adverse reactions.

When lidocaine hydrochloride is administered with other antiarrhythmic drugs such as phenytoin, procainamide, propranolol or quinidine, the cardiac effects may be additive or antagonistic and toxic effects may be additive. Phenytoin may stimulate the hepatic metabolism of lidocaine, but the clinical significance of this effect is not known.

### **ADVERSE REACTIONS**

Systemic reactions of the following types have been reported:

#### **Central Nervous System**

Nervousness, lightheadedness, dizziness, blurred or double vision, tinnitus, twitching or tremors, drowsiness, nausea and vomiting, sensation of heat, cold or numbness, convulsions, unconsciousness and respiratory depression or arrest.

#### **Cardiovascular System**

Myocardial depression, hypotension, bradycardia and cardiac arrest. There have been reports of A-V block in patients with diffuse intraventricular conduction disturbances, as well as reports of acceleration of conduction in the presence of atrial flutter, leading to a large increase in ventricular rate.

#### **Allergic Reactions**

Cutaneous lesions of delayed onset, urticaria, edema and other manifestations of allergy. The detection of sensitivity by skin testing is of doubtful value.

Adverse reactions were found to be dose-related. Toxic effects have been observed at concentrations over 6 mcg/mL. However, idiosyncratic reactions have been reported at low

doses in some patients.

Cross-sensitivity between lidocaine and procainamide or lidocaine and quinidine has not been reported.

### **SYMPTOMS AND TREATMENT OF OVERDOSAGE**

The symptoms of overdosage or idiosyncratic reactions are as described under **ADVERSE REACTIONS**.

Use of the drug should be discontinued if severe reactions occur. In the event of circulatory collapse, emergency resuscitative measures, such as oxygen, vasopressor drugs or cardiac massage, should be instituted. Cardiac pacemaker and defibrillator should be readily available. For severe convulsions, small doses of an ultra-short-acting barbiturate, or a short-acting muscle relaxant (if the patient is under anesthesia) may be used.

### **DOSAGE AND ADMINISTRATION**

Lidocaine hydrochloride may be administered by intravenous injection followed by intravenous infusion.

#### **General**

**NO MORE THAN 200 TO 300 MG OF LIDOCAINE HYDROCHLORIDE SHOULD BE ADMINISTERED DURING A ONE-HOUR PERIOD.**

**CAUTION:** In shock, heart failure, hepatocellular liver disease and in those over 70 years of age, reduce the dose recommended above for single injection and continuous infusion by one half and measure serum concentrations frequently (see **PRECAUTIONS**).

Intravenous infusion of the drug must be administered under constant ECG and blood pressure monitoring to avoid potential overdosage and toxicity. Intravenous infusion should be terminated as soon as the patient's basic cardiac rhythm appears to be stable or at the earliest signs of toxicity. As soon as possible, and when indicated, patients should be changed to an oral antiarrhythmic agent for maintenance therapy.

#### **For Direct Intravenous Injection**

For direct intravenous injection, the usual dose of lidocaine hydrochloride is 50 to 100 mg administered at an approximate rate of 25 to 50 mg/min. Sufficient time should be allowed to enable a slow circulation to carry the drug to the site of action. If the initial injection of 50 to 100 mg does not produce the desired response, a second dose may be repeated after five to ten

minutes.

### **For Continuous Infusion**

Following intravenous injection, lidocaine hydrochloride 0.2% solution may be administered by intravenous infusion at a rate of 1 to 4 mg/min (1/2 to 2 mL/min) (approximately 15 to 55 mcg/kg/min) in those patients in whom the arrhythmia tends to recur, and who are incapable of receiving oral antiarrhythmic therapy.

When fluid restriction is desirable, lidocaine hydrochloride 0.4% solution may be used at the rate of 1 to 4 mg/min (1/4 to 1 mL/min).

When administering lidocaine hydrochloride by continuous intravenous infusion, it is necessary to use an infusion pump or a precision volume control intravenous set.

Inspect bag by squeezing firmly. If leaks are found, discard. Use only if solution is clear. Must not be used in series connections. Do not add any additive to the solution.

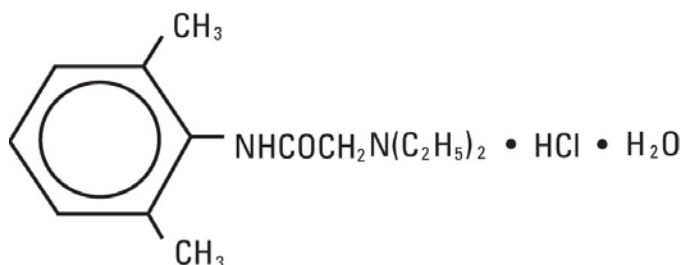
## PHARMACEUTICAL INFORMATION

### Drug Substance

**Proper Name** Lidocaine Hydrochloride USP

**Chemical Name** 2-(Diethylamino)-N-(2,6-dimethylphenyl)-acetamide monohydrochloride monohydrate

### Structural Formula



**Molecular Formula** C<sub>14</sub>H<sub>22</sub>N<sub>2</sub>O.HCl.H<sub>2</sub>O

**Molecular Weight** 288.82

### Description

Lidocaine hydrochloride USP is a white, odourless, crystalline powder which has a slightly bitter taste. It is very soluble in water and in alcohol, soluble in chloroform, and insoluble in ether. Melting point 77 to 78° C, pKa 7.86. The pH range of a 0.5% solution of lidocaine hydrochloride in water is 4.0 to 5.5.

### Composition

2% single-use syringes contain lidocaine hydrochloride (expressed as the hydrochloride salt) and sodium chloride sufficient to render the solution isotonic (6 mg/mL). They may contain sodium hydroxide and/or hydrochloric acid for pH adjustment. The pH range is 5.0 to 7.0.

Plastic bags contain lidocaine hydrochloride and dextrose monohydrate. No dilution is required.

## STABILITY AND STORAGE RECOMMENDATION

Store between 20 and 25°C. Protect from freezing. Avoid excessive heat.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.



Do not use unless the solution is clear and container or seal intact. Discard if it contains a precipitate.

For single-use, discard unused portion.

### **AVAILABILITY OF DOSAGE FORMS**

<b>Product name</b>	<b>Purpose</b>	<b>Container</b>	<b>Size</b>
2% Lidocaine Hydrochloride Injection USP	Single Intravenous Injection	LifeShield™ Abboject™ Syringe <sup>1</sup>	5 mL
		Ansy™ syringe <sup>2</sup>	5 mL
0.4% Lidocaine Hydrochloride and 5% Dextrose Injection USP	Continuous Intravenous Infusion	Plastic bag	250 mL and 500 mL

**1: LifeShield™ Abboject™ Syringe:** Flexible and reliable, the ready-to-use LifeShield™ Abboject™ syringe minimizes errors and protects caregivers and patients alike. It can be used for needle-free or shrouded needle access. The design features two pieces - a calibrated glass drug vial and a matching plastic syringe barrel with integral injector needle. Medication, fluid path, and needle are sterile and nonpyrogenic if caps and needle cover are undisturbed and package intact.

**2: Ansy™ Syringe:** The Ansy™ syringe is a proprietary delivery option offering one-piece, polypropylene plastic construction with a needle-free luer lock adapter. Ansy syringes are available prefilled with a wide range of emergency medications. Graduated markings on the syringe barrel conform to ISO standards and clearly show any drug remaining. Medication and fluid path are sterile and nonpyrogenic if protective cover is undisturbed and package intact.