

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

0.1% w/v Lidocaine Hydrochloride in 5% w/v Glucose Intravenous Infusion BP.

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine Hydrochloride 1.07g per 1000ml (0.107 % w/v)  
(equivalent to anhydrous Lidocaine Hydrochloride 1g per 1000ml (0.1% w/v))

Anhydrous Glucose 50g per 1000ml (5.00 % w/v)  
or  
Glucose Monohydrate 55g per 1000ml (5.50 % w/v)

For full list of excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Solution for infusion.

A clear, colourless, sterile aqueous solution.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

0.1% Lidocaine Hydrochloride in 5% Glucose Intravenous Infusion is indicated for the acute management of arrhythmias of ventricular origin, such as occur during cardiac surgery, myocardial infarction, etc.

##### 4.2 Posology and method of administration

###### Dosage

Distinguish between adults and the elderly and between different clinical indications. A bolus intravenous injection of Lidocaine usually precedes infusion. The usual infusion dosage is 20 to 50 micrograms/kg/minute by infusion. The individual infusion rate is decided with ECG and specialist advice.

Evidence of safety for use in children has not been established.

###### Administration

Route of administration is by intravenous infusion.

### 4.3 Contraindications

Use in patients with hypersensitivity to local anesthetics of the amide type.

Use in patients with Stokes-Adams syndrome or sinoatrial atrioventricular or intraventricular block, or cardiac decompensation or hypotension not dependent on tachyarrhythmias.

### 4.4 Special warnings and precautions for use

Side effects such as dizziness and drowsiness may occur. More severe effects e.g. convulsions, bradycardia, hypotension and respiratory arrest may occur from excessive dosage.

Lidocaine should only be used with great caution in patients with hypovolaemia, shock, severe liver or renal disease.

Administration of Lidocaine to eliminate ventricular ectopic beats without prior acceleration in heart rate may provoke more frequent and serious ventricular arrhythmias.

Evidence of safety for use in children has not been established.

This substance should only be used in specialised units having adequate monitoring and surveillance available and appropriate resuscitative equipment.

### 4.5 Interaction with other medicinal products and other forms of interaction

Drug interactions between Lidocaine and phenytoin; procainamide; disopyramide; barbiturates; benzodiazepines; pentobarbitone; propranolol; noradrenaline; isoprenaline; suxamethonium; tubocurarine and cimetidine; have been reported in the literature.

### 4.6 Pregnancy and lactation

Although there is no evidence from animal studies of harm to the foetus, Lidocaine Hydrochloride as with all drugs, should not be given during early pregnancy unless the benefits are considered to outweigh the risks.

### 4.7 Effects on ability to drive and use machines

Not advisable due to overriding medical condition.

### 4.8 Undesirable effects

Following administration of Lidocaine Hydrochloride mild side effects (dizziness and drowsiness) may be experienced. These disappear when the infusion is reduced or terminated. Toxic effects may be increased in cases of severe impairment of liver function, or pronounced liver dysfunction.

### 4.9 Overdose

Excessive dosage of Lidocaine Hydrochloride may result in serious side effects, namely convulsions, bradycardia, hypotension and respiratory arrest.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Lidocaine acts as an anti-dysrhythmic by membrane stabilisation. Lidocaine also has a local anaesthetic property.

### 5.2 Pharmacokinetic properties

When given intravenously Lidocaine plasma concentrations decline rapidly, with a half life of approximately ten minutes (elimination half life is approximately 2 hours). Lidocaine undergoes first pass metabolism in the liver and the metabolic products are excreted in the urine. Less than 10% of the dose is excreted unchanged by the kidneys.

### 5.3 Preclinical safety data

Not applicable.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Water for Injections.

### 6.2 Incompatibilities

Compatibilities should be checked when additives are used with Lidocaine Hydrochloride.

Do not transfuse blood through the same giving set.

### 6.3 Shelf Life

Unopened overpouch and container: 2 years.

The contents of the container must be used within three days of removing the container from the overpouch.

Once the container is opened, use immediately, discard any unused portion.

### 6.4 Special precautions for storage

Do not store above 25°C.

### 6.5 Nature and contents of container

This product is supplied in a single-dose container comprising a PVC bag sealed within a high density polyethylene or polypropylene pouch. The product will be supplied in 500 ml or 1000 ml containers.

## **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

For single use only, discard any unused portion.

Do not use unless solution is clear and the container is undamaged.

Read direction sheet before use.

Check additive compatibility before use.

For use under medical supervision.

Do not reconnect partially used bags.

## **7 MARKETING AUTHORISATION HOLDER**

Baxter Healthcare Ltd.,  
Caxton Way,  
Thetford,  
Norfolk,  
IP24 3SE,  
United Kingdom.

## **8 MARKETING AUTHORISATION NUMBER**

PA 0167/005/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 14<sup>th</sup> February 1978

Date of last renewal: 14<sup>th</sup> February 2003

## **10 DATE OF REVISION OF THE TEXT**

May 2007