

# **PRODUCT NAME: LIDOCAINE INJECTION BP 0.5% w/v**

## **Part II**

### **Summary of Product Characteristics**

#### **1. NAME OF THE MEDICINAL PRODUCT**

Lignocaine Hydrochloride Injection BP 0.5% w/v

#### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 10ml of solution contains 50mg (5mg in 1ml) of Lignocaine Hydrochloride (Lidocaine Hydrochloride).

#### **3. PHARMACEUTICAL FORM**

Solution for Injection.  
Clear colourless sterile solution.

#### **4. CLINICAL PARTICULARS**

##### **4.1 Therapeutic Indications**

As a local anaesthetic agent

##### **4.2 Posology and Method of Administration**

The dosage should be adjusted according to the response of the patient and the site of administration. The lowest concentration and smallest dose producing the required effect should be given in healthy adults. A maximum dose of 3mg/kg or 200mg, whichever is the lower, should not be exceeded.

Children and elderly or debilitated patients require smaller doses, commensurate with age and physical status.

Route of administration: Infiltration by injection. Intravenous.

##### **4.3 Contra-indications**

Known hypersensitivity to lignocaine or to other local anaesthetics of the amide type.

##### **4.4 Special Warning and Special Precautions for Use**

Great caution must be exercised to avoid accidental intravascular injection of this agent, since it may give rise to the rapid onset of toxicity, with marked restlessness, twitching, or convulsions, followed by coma with apnoea and cardiovascular collapse. Facilities for resuscitation should be available.

Absorption from mucosal surface e.g. respiratory tract may give rise to plasma concentrations similar to those produced by intravenous injection; great care should therefore be exercised when anaesthetizing mucous membranes or other highly vascular areas especially if these are inflamed or traumatized.

The continuous or repeated administration of this product may give rise to cumulative toxicity and tachyphylaxis.

This product may give rise to allergic manifestations.

The product should be used with caution in patients with epilepsy, impaired cardiac conduction, impaired respiratory function, or in those with impaired hepatic or renal function.

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

#### **4.5 Interactions with other Medicaments and other forms of Interaction**

Serum levels of lignocaine can be increased by the concurrent use of propranolol or cimetidine.

Action of lignocaine is antagonized by hypokalemia caused by acetazolamide, loop diuretics and thiazides.

Cardiac depressant effect of lignocaine are additive to those of other antiarrhythmic agents.

There is increased risk of ventricular arrhythmias with Quinupristine / dalfopristine. Avoid concomitant use.

Lignocaine prolongs the action of suxamethonium.

#### **4.6 Pregnancy and Lactation**

This product crosses the placenta, and may give rise to signs of toxicity in the neonate, including decreased muscle strength and tone, bradycardia, apnoea, and convulsions. This should be borne in mind when use is employed in obstetric analgesia.

Lignocaine should not be given during early pregnancy unless considered essential by the physician.

#### **4.7 Effects on ability to Drive and use Machines**

Where local anaesthesia affects areas of the body involved in driving or operating machinery, patients should be advised to avoid these activities until normal function is fully restored.

#### **4.8 Undesirable Effects**

Adverse reactions to lignocaine are rare and are usually the result of excessively high plasma concentrations due to inadvertent intravascular injection, rapid absorption or excessive dosage (see Overdosage below). Allergic reactions have been reported.

## 4.9 Overdose

Lignocaine may produce systemic toxicity as a result of the raised plasma concentrations, which ensue following overdosage, inadvertent intravascular injection or rapid absorption from the injection site. The systemic toxicity of lignocaine involves the central nervous systems and the cardiovascular system.

CNS excitation may manifest as nervousness, dizziness, tinnitus, blurred vision, tremors and convulsions. Excitation may be transient or it may not occur, and the first signs of toxicity may be drowsiness, loss of consciousness and respiratory failure. Cardiovascular effects are depressant and may include myocardial depression, hypotension, bradycardia and possibly cardiac arrest.

Treatment of systemic toxicity should be directed at arresting convulsions, maintaining the circulation and ensuring adequate ventilation. A patent airway must be established and oxygen administered, together with assisted ventilation if necessary. Convulsions may be controlled by intravenous injection of thiopentone 100 to 200mg or diazepam 5 to 10mg.

Alternatively, suxamethonium 50 to 100mg may be administered intravenously, together with endotracheal intubation and artificial respiration, provided that the facilities and skills are available for managing a fully paralysed patient. The circulation should be maintained with infusion of intravenous fluids. If hypotension is severe or persistent, a vasopressor such as ephedrine may be given intravenously.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic Properties

Lignocaine is a local anaesthetic of the amide type. It is used to provide local anaesthesia at various sites in the body and it acts by inhibiting the ionic fluxes required for the initiation and conduction of impulses, thereby stabilising the neuronal membrane. After absorption lignocaine may cause stimulation of the CNS followed by depression and in the cardiovascular system, it acts primarily on the myocardium where it may produce decreases in electrical excitability, conduction rate and force of contraction.

### 5.2 Pharmacokinetic Properties

Lignocaine is readily absorbed from the gastro-intestinal tract, from mucous membranes, and through damaged skin. It is absorbed from injection sites, including muscle, and its rate of absorption is determined by factors such as the site of administration and the tissue vascularity.

Lignocaine is bound to plasma proteins including  $\alpha$ -1-acid-glycoprotein. It crosses the blood-brain and placental barriers and is excreted in small amounts in breast milk.

Lignocaine is largely metabolized in liver and approximately 90% of lignocaine administered is excreted via urine as metabolites. The elimination half-life of lignocaine following intravenous injection is 1 to 2 hours but may be prolonged in patients with liver dysfunction.

Renal impairment dose not affect the clearance of lignocaine but may lead to accumulation of its active metabolites.

### **5.3 Preclinical Safety Data**

No further relevant information other than that, which is included in other sections of the Summary of Product Characteristics.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of Excipients**

Sodium chloride,  
Sodium hydroxide (as a 10% w/v solution) or dilute hydrochloric acid,  
Water for injections.

### **6.2 Incompatibilities**

Lignocaine caused precipitation of amphotericin, methohexitone sodium and sulphadiazine sodium in glucose injection.

### **6.3 Shelf life**

4 years.  
Once opened, use immediately.

### **6.4 Special Precautions for Storage**

Do not store above 25°C.

### **6.5 Nature and contents of container**

10ml clear glass ampoules, glass type I Ph. Eur. In cardboard cartons to contain 10 x 10ml ampoules.

### **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**

If only part used, discard the remaining solution.

## **7 NAME AND ADDRESS OF MARKETING AUTHORISATION HOLDER**

Antigen Pharmaceuticals Ltd.,  
Roscrea,  
Co. Tipperary.

## **8 MARKETING AUTHORISATION NUMBER**

PA 73/112/1

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

19 April 1994 / 19 April 1999

**10 DATE OF (PARTIAL) REVISION OF THE TEXT**

21 August 2006