## 1. NAME OF THE MEDICINAL PRODUCT

Lidocaine 2 % with preservative Injection.

# 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

**Each 1 ml contains 20.0 mg of lidocaine hydrochloride, corresponding to 16.2 mg lidocaine.**

# 3 PHARMACEUTICAL FORM

Solution for Injection.

## 4.1. Therapeutic indications

Lidocaine 2 % with preservative Injection is used as a local anaesthetic.

## 4.2. Posology and method of administration

Lidocaine 2 % with preservative Injection is used as a local anaesthetic when injected subcutaneously.

This solution is not intended for use intravenously. Solutions of lidocaine, which contain preservatives, should not be used for spinal, epidural, caudal or intravenous regional anaesthesia.

The dosage should be adjusted according to the response of the patient and the site of administration. The lowest concentration and the smallest dose producing the required effect should be given. The maximum dose for healthy adults should not exceed 200 mg corresponding to 10 mls or 5 cartridges.

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

The injection maybe used for infiltration in volumes of 1 ml to 10 ml.

## 4.3. Contra-indications

Know hypersensitivity to hydroxybenzoates and to anaesthetics of the amide type.

## 4.4. Special warnings and precautions for use

As with other local anaesthetics, lidocaine should be used with caution in patients with epilepsy, cardiac conduction disturbances, congestive cardiac failure, bradycardia or impaired respiratory function. Lidocaine is metabolised in the liver and it should be used with caution in patients with impaired hepatic function. Lidocaine should not be used in cases of acute porphyrias.

Patients with myasthenia gravis are particularly susceptible to the effects of local anaesthetics.

Facilities for resuscitation should be available when administering local anaesthetics.

The effect of local anaesthetics may be reduced if the injection is made into an inflamed or infected area.

This product contains 0.15-0.2 mmol (or 3.5-4.7 mg) sodium per cartridge. To be taken into consideration by patients on a controlled sodium diet

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

The clearance of lidocaine may be reduced by beta-adrenoceptor blocking agents and by cimetidine, requiring a reduction in the dosage of lidocaine.

## 4.6 Pregnancy and lactation

Although animal studies have revealed no evidence of harm to the foetus, lidocaine crosses the placenta and should not be administered during early pregnancy unless the benefits are considered to outweigh the risks.

Small amounts of lidocaine are secreted into breast milk and the possibility of an allergic reaction in the infant, albeit remote, should be borne in mind when using lidocaine in nursing mothers.

## 4.7 Effects on ability to drive and use machines

Where outpatient 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

In common with other local anaesthetics, adverse reactions to lidocaine are rare and are usually the result of raised plasma concentrations due to accidental intravascular injection, excessive dosage or rapid absorption from highly vascular areas, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Systemic toxicity mainly involves the central nervous system and/or the cardiovascular system.

CNS reactions may be excitatory and/or depressant and may manifest as nervousness, tremor, blurred vision, nausea and vomiting, followed by drowsiness, convulsions, coma and possible respiratory arrest. The excitatory reactions may be brief or may not occur at all, so that the first signs of toxicity may be drowsiness, followed by coma and respiratory failure.

Cardiovascular reactions are depressant and may manifest as hypotension, bradycardia, myocardial depression and possible cardiac arrest.

Allergic reactions are rare. They may be characterised by cutaneous lesions, urticaria, oedema or anaphylactoid reactions. Skin testing for allergy to lidocaine is not considered to be reliable.

Solutions of lidocaine, which contain preservatives, are not suitable for spinal, epidural or caudal anaesthesia. Adverse effects reported following unpreserved lidocaine solutions administered by this route include hypotension and isolated cases of bradycardia and cardiac arrest.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

### 4.9 Overdose

The effects of overdosage involve the central nervous system, where reactions may be excitatory and/or depressant and the cardiovascular system where the effects are depressant.

In the event of overdosage, immediate steps should be taken to maintain the circulation and respiration and to control convulsions.

A patent airway should be established and oxygen should be administered, together with assisted ventilation if necessary. The circulation should be maintained with infusions of plasma or intravenous fluids. Where further supportive treatment of circulatory depression is required, use of a vasopressor agent may be considered although this involves a risk of CNS excitation. Convulsions may be controlled by the intravenous administration of diazepam or thiopentone sodium, bearing in mind that anti-convulsant drugs may also depress respiration and the circulation. If cardiac arrest should occur, standard cardiopulmonary resuscitation procedures should be instituted.

Dialysis is of negligible value in the treatment of acute overdosage with lidocaine.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Local anaesthetic, ATC code: N01BB02.

Lidocaine is a local anaesthetic of the amide group. It is used to provide local anaesthesia at various sites in the body and it acts by inhibiting the ionic refluxes required for the initiation and conduction of impulses, thereby stabilising the neuronal membrane. In addition to blocking conduction in nerve axons in the peripheral nervous system, lidocaine has important effects on the central nervous system and cardiovascular system. After absorption, lidocaine may cause stimulation of the CNS followed by depression. 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

Lidocaine 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. Except for intravascular administration, the highest blood levels occur following intercostal nerve block and the lowest after subcutaneous administration. Lidocaine is bound to plasma proteins, including alpha-1-acid-glycoprotein. The drug crosses the blood-brain and placental barriers.

Lidocaine is metabolised in the liver and about 90 % of a given dose undergoes N-dealkylation to form monoethylglycinexylidide and glycinexylidide, both of which may contribute to the therapeutic and toxic effects of lidocaine. Further metabolism occurs and metabolites are excreted in the urine with less than 10 % of unchanged lidocaine. The elimination half-life of lidocaine following an intravenous bolus injection is one to two hours, but this may be prolonged in patients with hepatic dysfunction.

## 5.3 Preclinical safety data

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

## 6.1. List of excipients

Sodium Chloride
Methylhydroxybenzoate -E218 (1.7 mg/ml)
Propylhydroxybenzoate -E216 (0.3 mg/ml)
Water for Injections
Sodium Hydroxide (for pH adjustment)

## 6.2 Incompatibilities

Lidocaine causes precipitation of amphotericin, methohexitone sodium and sulphadiazine sodium in glucose injection. It is recommended that admixtures of lidocaine and glyceryltrinitrate should be avoided.

### 6.3 Shelf life

24 months

### 6.4. Special precautions for storage

Keep cartridges in the outer carton
Store below 25°C. Do not refrigerate or freeze

### 6.5. Nature and contents of container

Type 1 glass cartridges with siliconised grey non-aspirated chlorbutyl rubber plunger and an aluminium crimping cap with siliconised grey chlorbutyl membrane.

50 dental cartridges of 2ml in blister packs grouped in a cardboard box.

### 6.6. Special precautions for disposal

No special requirements

## 7. MARKETING AUTHORISATION HOLDER

hameln pharma ltd
Nexus, Gloucester Business Park
Gloucester, GL3 4AG
United Kingdom

## 8 MARKETING AUTHORISATION NUMBER(S)

01502 / 0071

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

03/08/2006

## 10 DATE OF REVISION OF THE TEXT

10/08/2020

## 11 DOSIMETRY (IF APPLICABLE)

# 12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)