Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lidocaine Hydrochloride 2% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml of solution contains 20mg of Lidocaine Hydrochloride (Lignocaine Hydrochloride).
Each 2 ml ampoule contains 40mg of Lidocaine Hydrochloride.
Each 5 ml ampoule contains 100mg of Lidocaine Hydrochloride.
Each 20 ml ampoule contains 400mg (0.4g) of Lidocaine Hydrochloride

For full list of excipients, see section 6.1.

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

Route of administration:

Adults: Infiltration by injection. Intravenous, Epidural.
Children: Infiltration by injection

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.

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

Paediatric population:
For Infiltration anaesthesia only
According to nature of procedure, up to 3 mg/kg (0.3 mL/kg of 1% solution) to a maximum of 200mg, repeated not more often than every 4 hours.

4.3 Contraindications

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

4.4 Special warnings and 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 when administering local anaesthetics.

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

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

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.

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 Cimetidine, requiring a reduction in the dosage of lidocaine.

Action of lidocaine is antagonized by hypokalemia cause by acetazolamide, loop diuretics and thiazides.

The cardiac depressant effect of lidocaine is additive to those of other antiarrythmic agents.

There is increased risk of ventricular arrythmias with quinupristine/dalfopristine. Avoid concomitant use.

Lidocaine prolongs the action of suxamethonium.

4.6 Fertility, 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.

Although animal studies have revealed no evidence of harm to the foetus, lidocaine should not be given during early pregnancy unless considered essential by the physician.

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 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

In common with other local anaesthetics, adverse reactions may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient.

Adverse reactions to lidocaine are rare and are usually the result of excessively high plasma concentrations due to inadvertent intravascular injection, rapid absorption or excessive dosage (see Overdose below).

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

Hypotension may accompany spinal and epidural anaesthesia. Isolated cases of bradycardia and cardiac arrest have also been reported.

CNS reactions may be excitatory and/or depressant and may manifest as nausea and vomiting, coma. 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.

Lidocaine may also result in methaemoglobinaemia.

Neurological complications of spinal anaesthesia include transient neurological symptoms such as pain of the lower back, buttock and legs. These symptoms usually develop within twenty-four hours of anaesthesia and resolve within a few days. Isolated cases of cauda equina syndrome, with persistent paraesthesia, bowel and urinary dysfunction, or lower limb paralysis have been reported following spinal anaesthesia with lidocaine and other similar agents. The majority of cases have been associated with hyperbaric concentrations of Lidocaine or prolonged spinal infusion.

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:

HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie
e-mail: medsafety@hpra.ie.

4.9 Overdose

Lidocaine 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 lidocaine 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. 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 5 to 10mg or Thiopental Sodium 100 to 200mg, bearing in mind that anti-convulsant drugs may also depress respiration and the circulation.

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 cardiac arrest should occur, standard cardiopulmonary resuscitation procedures should be instituted. If hypotension is severe or persistent, a vasopressor such as ephedrine may be given intravenously.

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 type. 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. After absorption lidocaine 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

Lidocaine 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.

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

Lidocaine is largely metabolised in liver and approximately 90% of lidocaine administered is excreted via urine as metabolites. The elimination half-life of lidocaine following intravenous injection is 1 to 2 hours but may be prolonged in patients with liver dysfunction. Renal impairment does not affect the clearance of lidocaine 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 (for pH adjustment only)
Water for injections.

6.2 Incompatibilities

Lidocaine caused precipitation of amphotericin, methohexital sodium and sulphadiazine sodium in glucose injection.
In the absence of compatibility studies, this product must not be mixed with other medicinal products.

6.3 Shelf life

Unopened: 4 years.

The product should be used immediately after opening.

6.4 Special precautions for storage

Do not store above 25^{o}C. Store in the original carton in order to protect from light.

6.5 Nature and contents of container

2ml, 5ml, 20ml clear glass ampoules, glass type 1, Ph. Eur. in cardboard cartons to contain:
10 x 2ml ampoules
10 x 5ml ampoules
10 x 20ml ampoules

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

For single use only.
Discard any unused content.
The product should be used immediately after opening.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Mercury Pharmaceuticals (Ireland) Ltd.
4045 Kingswood Road
Citywest Business Park
Co. Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0073/112/006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 April 1994

Date of last renewal: 19 April 2009

10 DATE OF REVISION OF THE TEXT

May 2017