Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lidocaine Hydrochloride Injection BP Minijet 2% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 20mg of Lidocaine Hydrochloride.

Each vial of 5ml contains 100mg of Lidocaine Hydrochloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
The clear, colourless, solution is contained in a USP Type I glass vial with an elastomeric closure and has a pH of between 5.0 and 7.0. The container is specially designed for use with the IMS Minijet injector supplied.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For local anaesthesia by infiltration, intravenous regional anaesthesia and nerve blocks.

By intravenous injection for the emergency management of ventricular arrhythmias, particularly after myocardial infarction and cardiac surgery.

4.2 Posology and method of administration

For local anaesthesia:
The dosage varies depending upon the area to be anaesthetised, vascularity of the tissues, number of neuronal segments to be blocked, individual tolerance and the anaesthetic technique. The lowest dosage needed to provide anaesthesia should be administered.

Adults: a maximum dose of 3 mg/kg or 200 mg, whichever is lower, should not be exceeded.

Children: the usual dose should not exceed 3 mg/kg.

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

For epidurals, a test dose should be administered at least 5 minutes before total dose to prevent inadvertent intravascular or subarachnoid injection.

For continuous epidural, caudal or paracervical anaesthesia, the maximal dose should not be repeated at intervals under 90 minutes.

For i.v. regional anaesthesia (Bier's block), the tourniquet should not be released until at least 20 minutes after administration.

For intravenous use in cardiac arrhythmias:
Adults: the usual dose is 50 to 100 mg administered intravenously under ECG monitoring. This dose may be injected at a rate of approximately 25 to 50 mg (2.5 to 5.0 ml 1% solution or 1.25 to 2.5 ml 2% solution) per minute. A sufficient period of time should be allowed to enable a slow circulation to carry the drug to the site of action. If the initial dose of 50 to 100 mg does not produce the desired response, a second dose may be given after 5 minutes. No more than 200 to 300 mg of lidocaine should be administered during a one hour period.

Following a single injection in those patients in whom arrhythmia tends to recur and who are incapable of receiving oral antiarrhythmic therapy, intravenous infusions of lidocaine may be administered at the rate of 1 to 4 mg/minute (20 to 50 mcg/kg/minute). IV infusions must be given under ECG monitoring to avoid potential overdosage and toxicity. The infusion should be terminated as soon as the patient's basic cardiac rhythm appears to be stable or at the earliest signs of toxicity. It should rarely be necessary to continue the infusion beyond 24 hours. As soon as possible, patients should be changed to an oral antiarrhythmic agent for maintenance therapy.

Children: experience with lidocaine is limited. A suggested paediatric dose is a loading dose of 0.8 to 1 mg/kg repeated if necessary up to 3-5 mg/kg, followed by continuous infusion of 10 to 50 mcg/kg/minute.

Elderly: doses may need to be reduced depending on age and physical state.

4.3 Contraindications

Lidocaine is contraindicated in patients with known hypersensitivity to local anaesthetics of the amide type or to any other component of the product and in patients with porphyria.

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

4.4 Special warnings and precautions for use

When used for local anaesthesia, it is important to protect against accidental intravascular injection and to bear in mind that absorption may be rapid from highly vascular areas especially if these are inflamed or traumatized.

Foetal bradycardia frequently follows paracervical block and may be associated with foetal acidosis. Foetal heart rate should always be monitored during paracervical anaesthesia.

Constant ECG monitoring is necessary during IV administration. Resuscitative equipment and drugs should be immediately available for the management of severe adverse cardiovascular, respiratory or central nervous system effects. If severe reactions occur, lidocaine should be discontinued.

Blood pressure should be monitored during epidural, caudal or paracervical anaesthesia.

Use with caution in patients with epilepsy, liver disease, congestive heart failure, severe renal disease, marked hypoxia, severe respiratory depression, hypovolaemia or shock and in patients with any form of heart block, atrioventricular conduction disturbance (in line with Sections 4.5 and4.8) or sinus bradycardia. Hypokalaemia, hyperkalaemia, hypoxia and disorders of acid-base balance should be corrected before treatment with lidocaine begins.

Blood pressure should be monitored during spinal anesthesia.

Administration of lidocaine to eliminate ventricular ectopicbeats without prior acceleration in heart rate may provoke more frequent and serious ventricular arrhythmias.

Continuous or repeated administration may give rise to cumulative toxicity and tachyphylaxis.

Intra-articular lidocaine may cause chondrotoxicity.

4.5 Interaction with other medicinal products and other forms of interactions

- Propranolol and cimetidine may reduce the renal and hepatic clearance of lidocaine, thus increasing toxicity.

- The cardiac depressant effects of lidocaine are additive to those of other antiarrhythmic agents particularly class I (e.g. kinidine, disopyramide) or class III (e.g. amiodarone, bretylium, sotalol or dofetilide). Caution should be exercised particularly in patients with cardiac decompensation.

- Potent inhibitor of cytochrome P450 3A4 enzymes (such as fluvoxamine and erythromycin) may cause an increase in lidocaine concentrations when administered concurrently. Because lidocaine possesses a narroe therapeutic

window, doses of lidocaine may need to be adjusted accordingly. Conversely, reduced serum lidocaine concentrations may result from drugs that may stimulate the hepatic metabolism of lidocaine (e.g. phenytoin).

- Hypokalaemia produced by acetazolamide, loop diuretics and thiazides antagonizes the effect of lidocaine.

- Propranolol, metoprol and nadolol may increase lidocaine levels by 20% to 30%. With concurrent beta-blocker therapy, monitor lidocaine levels more closely (at least every 24 hours) and adjust lidocaine infusion rates appropriately.

- Lidocaine is markedly bound to a l-acid glycoprotein (AAG). AAG concentrations may be reduced by oestrogens leading to a higher free fraction of lidocaine in women than in men and the free fraction is further increased during pregnancy and in women taking oral contraceptives or HRT.

- Concomitant administration of epidural morphine sulfate liposome with epidural lidocaine/epinephrine results in increased peak concentrations of morphine.

- Lidocaine prolongs the action of neuromuscular blocking agents such as suxamethonium and cisatracurium.

- Epidural administration of lidocaine in combination with clonidine, adrenaline or clonidine plus adrenaline significantly reduces the C_{max} of lidocaine.

4.6 Fertility, pregnancy and lactation

The safe use of lidocaine has not been established with respect to possible adverse effects upon foetal development. Lidocaine crosses the placenta and blood brain barrier. Lidocaine is excreted in breast milk and so should be used with caution in nursing women.

4.7 Effects on ability to drive and use machines

Not applicable; this preparation is intended for use only in emergencies.

4.8 Undesirable effects

Adverse effects are usually due to inadvertent intravenous administration or overdosage. Allergic reactions (including anaphylaxis) have been reported rarely.

The following systemic reactions have been reported in association with lidocaine:

Central nervous system:light-headedness, drowsiness, dizziness, apprehension, nervousness, euphoria, tinnitus, blurred or double vision, nystagmus, vomiting, sensations of heat, cold or numbness, twitching, tremors, paraesthesia, convulsions, unconsciousness, respiratory depression and arrest, nausea, headache, transient neurological symptoms i.e. pain and/or dysaesthesia in the buttocks or legs.

Cardiovascular system: arrhythmia, hypotension, cardiovascular collapse and bradycardia, which may lead to cardiac arrest. AV-block and myocardial depression.

Blood and the lymphatic system disorders: methaemoglobinaemia.

Psychiatric disorders: confusion and psychosis

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

Symptoms: reactions due to overdose with lidocaine (high plasma levels) are systemic and involve the central nervous and cardiovascular systems. Effects include medullary depression, tonic and clonic convulsions and cardiovascular collapse.

Treatment: institute emergency resuscitative procedures and administer the drugs necessary to manage the severe reaction. For severe convulsions, small increments of diazepam or an ultra-short acting barbiturate (thiopentone), or if not available, a short-acting barbiturate (pentobarbitone or quinalbarbitone), or if the patient is under anaesthesia, a short-acting muscle relaxant (suxamethonium) may be given intravenously. Patency of the airway and adequacy of ventilation must be assured.

Should circulatory depression occur vasopressors such as metaraminol may be used.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: C01BB 01 Antiarrhthmics, Class 1B and N01BB 02 local anaesthetic

Lidocaine stabilises the neuronal membrane and prevents the initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. The onset of action is rapid and the blockade may last up to 2 hours.

In the heart, lidocaine reduces automaticity by decreasing the rate of diastolic (phase 4) depolarisation. Lidocaine is considered as a class 1b (membrane stabilising) antiarrhythmic agent. The duration of the action potential is decreased due to blockade of the sodium channel and the refractory period is shortened.

5.2 Pharmacokinetic properties

Lidocaine is rapidly distributed to all body tissues. About 65% is plasma bound. Lidocaine crosses the placenta and the blood brain barrier. The plasma half life is 1.6 hours. About 80% of the dose is metabolised in the liver; less than 10% is found unchanged in the urine.

5.3 Preclinical safety data

Not applicable since lidocaine has been used in clinical practice for many years and its effects in man are well known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric Acid (for pH adjustment)
Sodium Chloride
Sodium Hydroxide (for pH adjustment)
Water for injections

6.2 Incompatibilities

In the absence of compatability studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

Unopened: 3 years.
Once 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

The solution is contained in a USP type I glass vial with an elastomeric closure which meets all the relevant USP specifications. The product is available as a 2% solution in a vial containing 5ml.

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 contents after first use.
The container is specially designed for use with the IMS Minijet injector.

7 MARKETING AUTHORISATION HOLDER

DLRC Pharma Services Limited
Chesterfield House
Clonmannon
Ashford
Wicklow
Ireland

8 MARKETING AUTHORISATION NUMBER

PA22684/008/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 September 1977

Date of last renewal: 08 September 2007

10 DATE OF REVISION OF THE TEXT

May 2019