SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Lidocaine Injection BP (21.3 mg/ml) Intravenous Injection (30mL)-Lignonir

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Lidocaine Hydrochloride BP 21.3 mg

Methylparaben BP 1.0 mg (As a preservative)

Water for Injections BP q.s.

3. PHARMACEUTICAL FORM

Pharmaceutical form: Injection

The visual and physical characteristic of the product: A Clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Lignocaine Injection is used as a local anaesthetic.

When injected into the skin, it causes loss of feeling before or during surgery

4.2 Posology and method of administration

Posology

Lignocaine Injection is used as a local anaesthetic when injected subcutaneously.

This solution is not intended for use intravenously. Solutions of Lignocaine, which containpreservatives, 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 effectshould be given. The maximum dose for healthy adults should not exceed 200 mg corresponding to20 mls.Children and elderly or debilitated patients require smaller doses, commensurate with age andphysical status. Dosages should be reduced in patients with cardiac and/or liver disease.The injection maybe used for infiltration in volumes of 1 ml to 60 ml.

Children

It is difficult to recommend a maximum dose of any drug for children, since this varies as afunction of age and weight. For children over 3 years of age who have a normal lean body massand normal body development, the maximum dose is determined by the child's age and weight.

For example, in a child of 5 years weighing 50 lbs the dose of Lignocaine HCl should not exceed75–100 mg (1.5 to 2 mg/lb).

The onset of anesthesia, the duration of anesthesia and the degree of muscular relaxation areproportional to the volume and concentration (ie, total dose) of local anesthetic used. Thus, anincrease in volume and concentration of Lignocaine Injection will decrease the onset of anesthesia,prolong the duration of anesthesia, provide a greater degree of muscular relaxation and increasethe segmental spread of anesthesia. Although the incidence of side effects with Lignocaine HCl isquite low, caution should be exercised when employing large volumes and concentrations, since theincidence of side effects is directly proportional to the total dose of local anesthetic agent injected.

Method of administration

Subcutaneously

4.3 Contraindications

Lidocaine is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type.

4.4 Special warnings and precautions for use

Lidocaine injections for infiltration and nerve block should be employed only by clinicians whoare well versed in diagnosis and management of dose-related toxicity and other acuteemergencies that might arise from the block to be employed and then only after ensuring theimmediate availability of oxygen, other resuscitative drugs, cardiopulmonary equipment, andthe personnel needed for proper management of toxic reactions and related emergencies (seealso adverse reactions and precautions). Delay in proper management of dose-related toxicity, underventilation from any cause and/or altered sensitivity may lead to the development ofacidosis, cardiac arrest and possibly death.

Lidocaine injection solutions contain methylparaben as a preservative. Local anaesthetic solutionscontaining antimicrobial preservatives (e.g. methylparaben) should not be used for epidural orspinal anaesthesia because the safety of these agents has not been established with regard tointrathecal injection, either intentional or accidental.

SPECIAL WARNINGS AND PRECAUTIONS:

Solutions of Lignocaine, which contain preservatives, are not suitable for spinal, epidural or caudalanaesthesia. Adverse effects reported following unpreserved Lignocaine solutions administered bythis route include hypotension and isolated cases of bradycardia and cardiac arrest.As with other local anaesthetics, Lignocaine should be used with caution in patients with epilepsy,cardiac conduction disturbances, congestive cardiac failure, bradycardia, severe shock, impairedrespiratory function or impaired renal function with a creatinine clearance of less than10mL/minute.

Lignocaine is metabolised in the liver and it should be used with caution in patients with impairedhepatic function. Lignocaine should not be used in cases of acute porphyrias.

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

Lignocaine HCl should be used with caution in persons with known drug sensitivities. Patientsallergic to para-aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc) may not havecross-sensitivity to Lignocaine HCl.

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 infectedarea. Certain local anaesthetic procedures may be associated with serious adverse reactions, regardless ofthe local anaesthetic drug used.

• Retrobulbar injections may rarely reach the cranial subarachnoid space, causing serious/severereactions, including cardiovascular collapse, apnoea, convulsions and temporary blindness

• Retro- and peribulbar injections of local anaesthetics carry a low risk of persistent ocular motordysfunction. The primary causes include trauma and/or local toxic effects on muscles and/ornerves.

The severity of such tissue reactions is related to the degree of trauma, the concentration of thelocal anaesthetic and the duration of exposure of the tissue to the local anaesthetic. For this reason,as with all local anaesthetics, the lowest effective concentration and dose of local anaestheticshould be used.

LIGNOCAINE INJECTIONS FOR INFILTRATION AND NERVE BLOCK SHOULD BE EMPLOYED ONLY BY CLINICIANS WHO ARE WELL VERSED IN DIAGNOSIS AND MANAGEMENT OF DOSE-RELATED TOXICITY AND OTHER ACUTE EMERGENCIESTHAT MIGHT ARISE FROM THE BLOCK TO BE EMPLOYED AND THEN ONLY AFTERENSURING THE IMMEDIATE AVAILABILITY OF OXYGEN,

OTHER RESUSCITATIVEDRUGS, CARDIOPULMONARY EQUIPMENT AND THE PERSONNEL NEEDED FORPROPER MANAGEMENT OF TOXIC REACTIONS AND RELATED EMERGENCIES.DELAY IN PROPER MANAGEMENT OF DOSE-RELATED TOXICITY,UNDERVENTILATION FROM ANY CAUSE AND/OR ALTERED SENSITIVITY MAY LEADTO THE DEVELOPMENT OF ACIDOSIS, CARDIAC ARREST AND, POSSIBLY, DEATH.

Lignocaine Injection is not recommended for use in neonates. The optimum serum concentration ofLignocaine required to avoid toxicity, such as convulsions and cardiac arrhythmias, in this agegroup is not known.Intra-articular infusions of local anesthetics following arthroscopic and other surgical procedures isan unapproved use, and there may be chances of chondrolysis in patients receiving such infusions.Chondrolysis mainly involve the shoulder joint; Gleno-humeral chondrolysis may occur in pediatric and adult patients following intra-articular infusions of local anesthetics for periods of 48to 72 hours. There is insufficient information to determine whether shorter infusion periods are notassociated with these findings. The time of onset of symptoms, such as joint pain, stiffness and lossof motion can be variable, but may begin as early as the 2nd month after surgery. Currently, there isno effective treatment for chondrolysis. Patients who experienced chondrolysis have requiredadditional diagnostic and therapeutic procedures and some required arthroplasty or shoulderreplacement.

Careful and constant monitoring of cardiovascular and respiratory (adequacy of ventilation) vitalsigns and the patient’s state of consciousness should be accomplished after each local anestheticinjection. It should be kept in mind at such times that restlessness, anxiety, tinnitus, dizziness,blurred vision, tremors, depression or drowsiness may be early warning signs of central nervoussystem toxicity.Since amide-type local anesthetics are metabolized by the liver, Lignocaine Injection should beused with caution in patients with severe hepatic disease, because of their inability to metabolizelocal anesthetics normally, are at greater risk of developing toxic plasma concentrations.Lignocaine Injection should also be used with caution in patients with impaired cardiovascularfunction since they may be less able to compensate for functional changes associated with theprolongation of A-V conduction produced by these drugs.Many drugs used during the conduct of anesthesia are considered potential triggering agents forfamilial malignant hyperthermia. Since it is not known whether amide-type local anesthetics maytrigger this reaction and since the need for supplemental general anesthesia cannot be predicted inadvance, it is suggested that a standard protocol for the management of malignant hyperthermiashould be available.Early unexplained signs of tachycardia, tachypnea, labile blood pressure and metabolic acidosismay precede temperature elevation.

Successful outcome is dependent on early diagnosis, promptdiscontinuance of the suspect triggering agent(s) and institution of treatment, including oxygentherapy, indicated supportive measures and dantrolene (consult dantrolene sodium intravenouspackage insert before using).

Use in the Head and Neck Area

Small doses of local anesthetics injected into the head and neck area, including retrobulbar, dental and stellate ganglion blocks, may produce adverse reactions similar to systemic toxicity seen withunintentional intravascular injections of larger doses. Confusion, convulsions, respiratorydepression and/or respiratory arrest, and cardiovascular stimulation or depression may occur. Thesereactions may be due to intra-arterial injection of the local anesthetic with retrograde flow to thecerebral circulation. Patients receiving these blocks should have their circulation and respirationmonitored and be constantly observed. Resuscitative equipment and personnel for treating adversereactions should be immediately available. Dosage recommendations should not exceeded

4.5 Interaction with other medicinal products and other forms of interaction

The clearance of Lignocaine may be reduced by beta-adrenoceptor blocking agents (e.g.propranolol) and by cimetidine,requiring a reduction in the dosage of Lignocaine. Increase inserum levels of Lignocaine may also occur with anti-viral agents (e.g. amprenavir, atazanavir,darunavir, lopinavir).Lignocaine should be used with caution in patients receiving other local anaesthetics or agentsstructurally related toamide-type local anaesthetics (e.g. anti-arrhythmics, such as mexiletine),since the systemic toxic effects are additive.Specific interaction studies with Lignocaine and class III anti-arrhythmic drugs (e.g. amiodarone)have not been performed, but caution is advised. There may be an increased risk of ventriculararrhythmia in patients treated concurrently with antipsychotics which prolong or may prolong theQT interval (e.g. pimozide, sertindole, olanzapine, quetiapine,zotepine), or 5HT3 antagonists (e.g.tropisetron, dolasetron).Concomitant use of quinupristin/dalfopristin should be avoided.There may be an increased risk of enhanced and prolonged neuromuscular blockade in patientstreated concurrently with muscle relaxants (e.g. suxamethonium).

4.6 Fertility, pregnancy and lactation

Pregnancy

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

Lignocaine given by local perineal infiltration prior to delivery crosses rapidly into the foetal circulation. Elevated Lignocaine levels may persist in the newborn for at least 48 hours afterdelivery. Foetal bradycardia or neonatal bradycardia, hypotonia or respiratory depression mayoccur.

Lactation

Small amounts of Lignocaine are secreted into breast milk and the possibility of an allergic reactionin the infant, albeit remote, should be borne in mind when using Lignocaine 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 operatingmachinery, patients should be advised to avoid these activities until normal function is fullyrestored.

4.8 Undesirable effects

In common with other local anaesthetics, adverse reactions to Lignocaine are rare and are usuallythe result of raised plasma concentrations due to accidental intravascular injection, excessivedosage 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

Immune system disorders

Hypersensitivity reactions (allergic or anaphylactoid reactions, anaphylactic shock)

Skin testing for allergy to Lignocaine is not considered to be reliable.

Nervous & Psychiatric disorders

Neurological signs of systemic toxicity include dizziness or light-headedness, nervousness, tremor,circumoralparaesthesia, tongue numbness, drowsiness, convulsions, coma.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 possiblerespiratory arrest. The excitatory reactions may be brief or may not occur at all, so that the firstsigns of toxicity may be drowsiness, followed by coma and respiratory failure. Cardiovascularreactions are depressant and may manifest as hypotension, bradycardia, myocardial depression andpossible cardiac arrest.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 national reporting system.Allergic reactions are rare. They

may be characterised by cutaneous lesions, urticaria, oedema oranaphylactoid reactions. Skin testing for allergy to lidocaine is not considered to be reliable.

Eye disorders

Blurred vision, diplopia and transient amaurosis may be signs of Lignocaine toxicity.

Bilateral amaurosis may also be a consequence of accidental injection of the optic nerve sheathduring ocular procedures.Orbital inflammation and diplopia may occur following retro- or peribulbaranaesthesia

Ear and labyrinth disorders

Tinnitus, hyperacusis

Cardiac and vascular disorders

Cardiovascular reactions are depressant and may manifest as hypotension, bradycardia, myocardialdepression,cardiac arrhythmias and possibly cardiac arrest or circulatory collapse.

Respiratory, thoracic or mediastinal disorders

Dyspnoea, bronchospasm, respiratory depression, respiratory arrest

Gastrointestinal

Nausea, vomiting

Skin & subcutaneous tissue disorders

Rash, urticaria, angioedema, face oedema

4.9 Overdose

Symptoms of acute systemic toxicity

Central nervous system toxicity presents with symptoms of increasing severity. Patients maypresent initially with circumoralparaesthesia, numbness of the tongue, light-headedness,hyperacusis and tinnitus. Visual disturbance and muscular tremors or muscle twitching are moreserious and precede the onset of generalised convulsions. These signs must not be mistaken forneurotic behaviour. Unconsciousness and grand mal convulsions may follow, which may last froma few seconds to several minutes. Hypoxia and hypercapnia occur rapidly following convulsions due to increased muscular activity, together with the interference with normal respiration and lossof the airway. In severe cases, apnoea may occur. Acidosis increases the toxic effects of localanaesthetics.Effects on the cardiovascular system may be seen in severe cases. Hypotension, bradycardia,arrhythmia and cardiac arrest may occur as a result of high systemic concentrations, withpotentially fatal outcome.Recovery occurs as a consequence of redistribution of the local anaesthetic drug from the centralnervous system, and metabolism and may be rapid unless large amounts of the drug have beeninjected.

Treatment of acute toxicity

If signs of acute systemic toxicity appear, injection of the local anaesthetic should be stoppedimmediately.Treatment will be required if convulsions and CNS depression occurs. The objectives of treatmentare to maintain oxygenation, stop the convulsions and support the circulation.A patent airway should be established and oxygen should be administered, together with assistedventilation (mask and bag) if necessary. The circulation should be maintained with infusions ofplasma or intravenous fluids. Where further supportive treatment of circulatory depression isrequired, use of a vasopressor agent may be considered although this involves a risk of centralnervous system excitation.

If the convulsions do not stop spontaneously in 15-20 seconds, they may be controlled by theintravenous administration of diazepam or thiopentone sodium, bearing in mind that anticonvulsantdrugs 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 Lignocaine.

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 atvarious 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 blockingconduction in nerve axons in the peripheral nervous system, lidocaine has important effects on thecentral nervous system and cardiovascular system. After absorption, lidocaine may cause stimulationof the CNS followed by depression. In the cardiovascular system, it acts primarily on themyocardium where it may produce decreases in electrical excitability, conduction rate and force ofcontraction

5.2 Pharmacokinetic properties

Lignocaine is absorbed from injection sites including muscle and its rate of absorption isdetermined by factors such as the site of administration and the tissue vascularity. Except forintravascular administration, the highest blood levels occur following intercostal nerve block andthe lowest after subcutaneous administration. Lignocaine is bound to plasma proteins, includingalpha-1-acid-glycoprotein. The drug crosses the blood-brain and placental barriers.

Lignocaine is metabolised in the liver and about 90 % of a given dose undergoes N-dealkylation toform monoethylglycinexylidide and glycinexylidide, both of which may contribute to thetherapeutic and toxic effects of Lignocaine. Further metabolism occurs and metabolites areexcreted in the urine with less than 10 % of unchanged Lignocaine.

5.3 Preclinical safety data

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride

Methyl Paraben

Water for Injection

6.2 Incompatibilities

Lidocaine causes precipitation of amphotericin, methohexitone sodium and sulphadiazinesodium in glucose injection. It is recommended that admixtures of lidocaine and glyceryl**trinitrate should be avoided.**

6.3 Shelf life

2 years from the date of manufacturing.

6.4 Special precautions for storage

Store in cool, dark place. Do not freeze.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Container: Glass bottle USP Type-IIClosure: Flip off seal & rubber stopper30 ml solution is filled in 30 ml glass vial and sealed with grey butyl rubber stopper and chocolatebrown coloured flip off aluminium seal. Such 10 sealed vials are packed in a carton with pigeonPartition.

6.6 Special precautions for disposal <and other handling>

Not known

7. MARKETING AUTHORISATION HOLDER

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