LIDOCAINE INJECTION BP 2%

POM

COMPOSITION:

Each ml contains:

Lidocaine Hydrochloride BP	21.3 mg
Sodium Chloride BP	6 mg
Methyl Paraben BP	1 mg
(As Preservative)	
Water for Injections BP	Q.S.

THERAPEUTIC CLASS:

Anaesthetic

PHARMACOLOGICALACTIONS:

Pharmacology: Lidocaine blockes activated (open) and inactivated cardiac sodium channel and decreases its automaticity thereby stabilizes the neuronal membrane and prevents the initiation and conduction of nerve impulses, thereby effecting local anaesthetic action.

Pharmacokinetic: During the first 1/2 hr after an IV injection the blood level of Lidocaine declines with a half-life of 7-10 min due to the rapid distribution to various tissues, including the heart. After this initial phase the half-life is 90-120 min (metabolism and excretion). During continuous infusion, steady-state is reached after 6-8 hrs.

Lidocaine is metabolised mainly in the liver and excreted via the kidneys. Approximately 90% of administered Lidocaine is excreted in the form of various metabolites while < 10% is excreted unchanged. The principal metabolites, monoethyl glycinexylidide and glycinexylidide also possess antiarrhythmic action, but to less extent.

INDICATIONS:

Production of local or regional anaesthesia by infiltration techniques: IV regional anaesthesia; by peripheral nerve block techniques, eg intercostal blocks; major plexus blocks, eg brachial plexus and by epidural and subarachnoid blocks. Lidocaine is used as a pre-operative infusions to decrease post-operative pain.

CONTRAINDICATIONS:

Allergy or hypersensitivity to amide-type local anaesthetics or other components of the injection solution which may be present. Detection of suspected hypersensitivity by skin testing is of limited value.

Local anaesthetics are contraindicated for epidural and spinal anaesthesia in patients with uncorrected hypotension and in those with coagulation disorders or receiving anticoagulation treatment.

Local anaesthetic techniques must not be used when there is inflammation and/or sepsis in the region of the proposed injection and in the presence of septicaemia.

SPECIAL PRECAUTIONS:

When any local anaesthetic agent is used, resuscitative equipment and drugs, including oxygen, should be immediately available in order to manage possible adverse reactions involving the cardiovascular, respiratory or central nervous systems. Injection should always be made slowly with frequent aspirations to avoid inadvertent intravascular injection, which can produce toxic effects. The safety and effectiveness of Lidocaine depend on proper dosage, correct technique and adequate precautions. Standard textbooks should be consulted regarding specific techniques and precautions for various regional anaesthetic procedures. The lowest dosage that results in effective anaesthesia should be used. Repeated injection of Lidocaine Injection may cause accumulation of Lidocaine or its metabolites and result in toxic effects. Debilitated, elderly or acutely ill patients should be given reduced doses commensurate with their age and physical status. Local anaesthetics should be given with great caution to patients with preexisting abnormal neurological conditions. The possibility of hypotension and bradycardia following epidural or subarachnoid blockade should be anticipated and precautions taken, including the prior establishment of an IV line and the availability of vasopressor drugs and oxygen. Since Lidocaine is metabolised in the liver and excreted via the kidneys, the possibility of drug accumulation should be considered in patients with hepatic and/or renal impairment. Lidocaine should be given with caution in patients with known drug sensitivities. Patients allergic to ester derivatives of para-aminobenzoic acid (procaine, tetracaine, benzocaine, etc) have not shown cross-sensitivity to agents of the amide type. Lidocaine should be used with caution in patients with genetic predisposition to malignant hyperthermia as the safety of amide local anaesthetic agents in these patients has not been fully established. Lidocaine should be given with great caution to patients with severe bradycardia, cardiac conduction disturbances or severe digitalis intoxication. Inadvertent intravascular or subarachnoid injection of small doses of local anaesthetics injected into the head and neck area, including retrobulbar, dental and stellate ganglion blocks, may produce adverse reactions similar to systemic toxicity seen with unintentional intravascular injections of larger doses. Clinicians who perform retrobulbar blocks should be aware that there have been reports of respiratory arrest following the use of local anaesthetic injections for retrobulbar block. Prior to retrobulbar block, necessary equipment, drugs and personnel should be immediately available as with all other regional procedures.

Use in pregnancy: The safe use of Lidocaine during pregnancy has not been established. Lidocaine has, however, been used extensively for surgical procedures during pregnancy with no reports of ill effects to mother or foetus. Lidocaine has been effectively used for obstetrical analgesia and adverse effects on the course of labour or delivery are rare. After epidural administration of Lidocaine to women in labour, Lidocaine crosses the placental barrier. However, concentrations in umbilical veins are lower than those found in the maternal circulation. Adrenaline-free solutions should be used during labour for paracervical or pudendal blocks. Note: Paracervical blocks may be associated with foetal bradycardia. Foetal bradycardia frequently follows paracervical block and may be associated with foetal acidosis and hypoxia. Occasional cases of perinatal morbidity and mortality have been reported. When the recommended dose is exceeded the risk of foetal bradycardia increases.

Use in lactation: Lidocaine passes into breast milk. The amount of Lidocaine appearing in breast milk from a nursing mother receiving parenteral Lidocaine is unlikely to lead to a significant accumulation of the parent drug in the breastfed infant. The remote possibility of an idiosyncratic or allergic reaction in the breastfed infant from Lidocaine remains to be determined.

WARNINGS:
Local anaesthetics react with certain, metals and cause the release of their respective ions which, if injected may cause severe local irritation. Adequate precautions should be taken to avoid prolonged contact between Lidocaine Injection solutions and metal surfaces, eg metal bowls, cannulae and syringes with metal parts. Solutions showing discolouration and unused portions of solutions from ampoules should be discarded. Polyethylene ampoules cannot be autoclaved.

ADVERSE EFFECTS:
Reactions to Lidocaine are similar in character to those observed with other local anaesthetics of the amide type. Adverse reactions may be due to high plasma levels as a result of excessive dosage, rapid absorption, delayed elimination or metabolism, or inadvertent intravascular injection. Pronounced acidosis or hypoxia may increase the risk and severity of toxic reactions. Such reactions are systemic in nature and involve the central nervous system and/or the cardiovascular system. Inadvertent subarachnoid injection may lead to cardiovascular collapse, CNS depression and respiratory arrest.
More Common Reactions: Nervousness, dizziness, blurred vision, tremor, drowsiness, tinnitus, numbness, disorientation, nausea and vomiting may occur.
Less Common Reactions: More serious but less common reactions that reflect an overdosage of Lidocaine are convulsions, unconsciousness, respiratory depression or arrest, hypotension, cardiovascular collapse and bradycardia which may lead to cardiac arrest.
Allergy: Allergy to amide-type local anaesthetics is very rare but may present as allergic dermatitis, bronchospasm or anaphylaxis.
Neurological Reaction: The incidence of adverse neurological actions directly caused by the use of local anaesthetics is very low.
Neurological reactions may be related to the total dose of the local anaesthetic administered and are also dependent upon the particular drug used, the route of administration and the physical status of the patient. Many of these effects may be related to local anaesthetic techniques, with or without contribution from the drug. Neurological reactions after regional anaesthesia have included persistent anaesthesia, paraesthesia, weakness, paralysis of the lower extremities and loss of sphincter control.

DOSAGE & ADMINISTRATION:
The lowest dosage that results in effective anaesthesia should be used and should be based on the status of the patient and the type of regional anaesthesia intended.
Adults weighing an Average of 70 kg: Various Anaesthetic Procedures: Recommended Dosage: Infiltration: 10 ml.
Epidural Blocks: Lumbar Anaesthesia: 5-10 ml. The dose is determined by the number of segments to be anaesthetised (2-3 ml/segment).
Note: Recommended Dosage: The previously-suggested concentrations and volumes serve only as a guide. Toxic doses vary widely between patients and toxic effects may occur after any local anaesthetic procedure. Careful observation of the patient must therefore be maintained. It is recommended that the dose of Lidocaine at any one time should not exceed 3mg/kg.
However, the dose administered must be tailored to the individual patient and procedure, and the maximum doses given should be used as a guide only.
Only single dose containers should be used for epidural and IV regional anaesthesia and for peripheral nerve block.
Hypotension: During thoracic, lumbar and caudal epidural anaesthesia, a marked fall in blood pressure and/or intercostal paralysis may be seen, possibly due to the use of excessive doses, improper positioning of the patient or accidental disposition of the anaesthetic within the subarachnoid space. Hypotension and bradycardia may occur as a result of sympathetic blockade.
Children: For children, a reduced dosage based on body weight or surface area should be used. The dosage should be calculated for each patient individually and modified in accordance with the physician's experience and knowledge of the patient.
In order to minimize the possibility of toxic effects, the use of Lidocaine Injection 0.5% or 1% solutions is recommended for most anaesthetic procedures involving paediatric patients.
Elderly: A reduction in dosage may be necessary for elderly patients especially those with compromised cardiovascular and/or hepatic function. In epidural anaesthesia, a smaller dose may provide adequate anaesthesia.
Impaired Hepatic function: In epidural anaesthesia, a smaller dose may provide adequate anaesthesia.
Impaired Renal Function: Impairment of renal function is unlikely to affect Lidocaine clearance in the short-term (24 hrs). However, toxicity due to accumulation may develop with prolonged or repeated administration.

DRUG INTERACTIONS:
Antiarrhythmic Drugs: Local anaesthetics of the amide type, eg Lidocaine, should be used with caution in patients receiving antiarrhythmic drugs since potentiation of cardiac effects may occur.
Beta-Adrenoreceptor Antagonists: Propranolol and metoprolol reduce the metabolism of IV administered Lidocaine and the possibility of this effect with other -adrenergic blockers should be kept in mind.
Cimetidine: Cimetidine reduces the clearance of IV administered Lidocaine and toxic effects due to high serum Lidocaine levels have been reported when these 2 drugs have been administered concurrently.
Anticonvulsive Agents: Diphenylhydantoin and other antiepileptic drugs, eg phenobarbitone, primidone and carbamazepine appear to enhance the metabolism of Lidocaine but the significance of this effect is not known.
Diphenylhydantoin and Lidocaine have additive cardiac depressant effects.

PRESENTATION:
Vial Pack.

STORAGE CONDITION:
Store below 30°C. Protect from light.

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