Vaxcel®

LIGNOCAINE 2%
INJECTION

MAL10053667AZ

COMPOSITION:
Each ml contains
Lignocaine Hydrochloride 20mg

Methylparaben 0.18% w/v as preservative.

PRESENTATION:
Clear, colorless solution, essentially free from visible evidence of contamination.

INDICATIONS:
For local or regional anaesthesia, peripheral nerve block, infiltration anaesthesia and diagnostic or therapeutic block.

MECHANISMS OF ACTION:
Lignocaine is local anaesthetics of the amide type which is thought to act within the sodium channels of the nerve membrane. Like other local anaesthetics, it causes reversible blockade of impulse propagation along nerve fibers by preventing the inward movement of sodium ions through the nerve membrane. It produces reversible loss of sensation by preventing or diminishing the conduction of sensory nerve impulses near the site of their application. Lignocaine is readily absorbed through mucous membrane. It exerts its effect in the form of non-ionised base. It tends to interfere with the process to the generation of the nerve action potential namely the large transient increase in the permeability of the membrane to sodium ions that is produced by a slight depolarization of the membrane. As the anaesthetic action progressively develops in a nerve, the threshold for electrical excitability gradually increases and the safety factor for conduction decreases. When this action is sufficiently well developed, block of conduction is produced.

PHARMACOKINETICS:
Following intravenous injection, the blood level of lignocaine declines with a half-life of seven to ten minutes within the first half hour due to a rapid distribution into various tissues including the heart. After this initial phase, the half-life is 90-120 minutes (metabolism and excretion). During a continuous infusion, the steady state is achieved after six to eight hours. Metabolism is mainly by N-dealkylation and hydrolysis in the liver. Excretion is via the kidneys. Approximately 90% of the dose is excreted as metabolites and less than 10% is excreted unchanged. The principal metabolites also possess antiarrhythmic activity, but to a lesser extent.

DOSAGE AND ADMINISTRATION:
For local anaesthetic:
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 anaesthesia technique. The lowest dosage needed to provide anaesthesia should be administered.

For SC / IM use:
Adult:

Procedure	Total Dose (mg)
Infiltration - Percutaneous	5 - 300
Peripheral nerve block - Brachial - Intercostal - Paracervival - Paravertabral - Retrobulbar	 225 - 300 30 100 (may be repeated if necessary at intervals of not less than 90 minutes) 30 - 50 120 - 200
Sympathetic nerve block - Cervical (stellate ganglion) - Transtracheal	 50 80 - 120 (in addition a 4% spray to the pharynx may be required to achieve complete analgesia)

Usual pediatric dose:
Local infiltration: Up to 4.5mg per kg body weight as a 0.25 to 0.5% solution.
Nerve block: Up to 4.5mg per kg of body weight as a 0.5 to 1% solution.

Note: Dosage must be individualized by physician, based on patients age and weight. For local infiltration, concentration of 0.25% to 0.5% are recommended for use in infants; concentrations of 0.5% are recommended for other pediatric patients.

ROUTE OF ADMINISTRATIONS:
Administered by subcutaneous or intramuscular injection.

CONTRAINDICATIONS:
It is contraindicated to patients with known hypersensitivity to Lignocaine HCl or local anaesthetics of amide type. Local anaesthetics are contraindicated for epidural and spinal anaesthesia in patient with uncorrected hypotension or coagulation disorder or in patients receiving anticoagulant treatment. It should not be used when there is inflammation or sepsis in the region of proposed injection or in the presence of septicaemia.

SIDE EFFECTS:
Local anaesthetics may produce systemic adverse effects as a result of the raised plasma concentrations which ensure when the rate of absorption into the circulation exceeds the rate of breakdown, example after by absorption of large amounts through mucous membranes; damaged skin or from highly vascular areas; accidental IV injection; excessive or too rapid dose. Adverse effects may also occur due to the addition of vasoconstrictors. The systemic toxicity of local anaesthetics mainly involves the central nervous system and the cardio-vascular system. Excitation of the CNS may be manifested by restlessness, excitement, nervousness, dizziness, tinnitus, blurred vision, nausea and vomiting, muscle twitching, tremors and convulsions. Numbness of the tongue and perioral region may appear as an early sign of systemic toxicity.
Excitation may be transient and followed by depression with drowsiness, respiratory failure and coma. There may be simultaneous effects on the cardiovascular system with myocardial depression and peripheral vasodilation resulting in hypotension and bradycardia; arrhythmias and cardiac arrest may occur. Hypotension often accompanies spinal and epidural anaesthesia inappropriate positioning of the patient may be a contributory factor for women in labour. Some local anaesthetics cause methaemoglobinaemia.
Fetal intoxication has occurred after the use of local anaesthetics in labour, either as a result of transplacental diffusion or after accidental injection of the fetus.
Adverse effects may also be caused by vasoconstrictors given with the anaesthetic.

Neurologic:
The incidence of adverse reactions associated with the use of local anaesthetics may be related to the total dose of local anaesthetic administered and are also dependent on the particular drug used, the route of administration and the physical status of the patient.

Haemodynamic:
Regional anaesthesia may lead to maternal hypotension.

Allergic:
Allergic reactions are characterised by cutaneous lesions, urticaria, oedema or anaphylactoid reactions. Allergy to amide-type local anaesthetics is very rare. The detection of sensitivity by skin testing is of doubtful value.

SYMPTOMS AND TREATMENTS FOR OVERDOSAGE:
Overdosage:
In anaesthesia, acute emergencies associated with the use of lignocaine are normally related to high plasma levels or unintended subarachnoid injection. Toxic symptoms may present following a seemingly normal dose as there is a wide variant in patient response to lignocaine. Treatment of toxicity should be to discontinue administration of lignocaine. Adequate ventilation of the patient (including oxygen if necessary) should be ensured and convulsions should be arrested if present (see Management of Adverse Effects).

Management of Adverse Effects:
In the case of severe effects, discontinue use immediately. Institute emergency resuscitative procedures and administer the emergency drugs necessary to manage the situation. For severe convulsions, small increments of diazepam or a short acting barbiturate such as thiopentone should be administered. If not available, pentobarbitone may be given. If convulsions interfere with respiration and are not controlled by specific anticonvulsants, suxamethonium may be given to paralyse the patient, in conjunction with artificial respiration. Should circulatory depression occur, vasopressor drugs such as ephedrine or metaraminol may be used.

WARNING AND PRECAUTION:
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. Because of the possibility of hypotension and bradycardia following major blocks, an IV cannula should be inserted before the local anaesthetic is injected. Delay in proper management of dose-related toxicity, under ventilation from any cause and / or altered sensitivity may lead to the development of acidosis, cardiac arrest and death.
Injection should always be made slowly with frequent aspirations to avoid inadvertent intravascular injection which can produce cerebral symptoms even at low doses.
Careful and constant monitoring of cardiovascular and respiratory vital signs and the patient's state of consciousness should be accomplished after each local anaesthetic injection. It should be kept in mind that at such times restlessness, anxiety, tinnitus, dizziness, blurred vision, tremors, depression or drowsiness may be early warning signs of CNS toxicity.
Central nerve blocks may cause cardiovascular depression, especially in the presence of hypovolemia. Epidural anaesthesia should be used with caution in patients with impaired cardiovascular function. Epidural anaesthesia may lead to hypotension and bradycardia.
Vaxcel Lignocaine 2% Injection should be used with caution in the treatment of patients with hypovolemia, severe congestive heart failure, shock and all forms of heart block. In patients with sinus bradycardia or incomplete heart block, the administration of Vaxcel Lignocaine 2% Injection for the elimination of ventricular ectopic beats, without prior acceleration in the heart rate (eg, by atropine, isoproterenol or electric pacing), may promote more frequent and serious ventricular arrhythmias or complete heart block.
Lignocaine should not be given to patients with hypovolemia, complete heart block or other conduction disturbances. They should be given cautiously to the elderly; to the debilitated, to children, and to patients with epilepsy, impaired cardiac conduction or respiratory function, shock or hepatic impairment; patients with myasthenia gravis are particularly susceptible to the effects of local anaesthetic. It should be use with caution in patients with congestive heart failure, bradycardia or respiratory depression. Lignocaine is metabolised in the liver and must be given with caution to patients with hepatic insufficiency. Metabolites of lignocaine may accumulate in patients with renal impairment.
Techniques epidural or spinal block should not be used in patients with cerebrospinal diseases, cardiogenic or hypovolemic shock, or altered coagulation status.
They should not be injected into or applied to inflamed or infected tissues or to damage skin or mucosa. The injection should not be too rapid to avoid inadvertent intravascular injection. Solution containing adrenaline should not be used for producing anaesthesia, because the profound ischemia may lead to gangrene.
Intramuscular injection of lignocaine may increase creatine phosphokinase concentrations that can interfere with the diagnosis of acute myocardial infarction. Use with severely traumatised mucosa and / or sepsis in the region of proposed application.

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 Vaxcel Lignocaine 2% Injection solution and metal surfaces e.g., metal bowls, cannulae and syringes with metal parts.

Use in pregnancy:
The safe use of lignocaine during pregnancy has not been established with respect to adverse effects upon foetal development. Careful consideration should be given before administering lignocaine, particularly during early pregnancy. In obstetrics, if vasopressor drugs are used to correct hypotension the obstetrician should be warned that some oxytocic drugs have additive hypertensive effects and rupture of a cerebral blood vessel may occur during the postpartum period.

Use in lactation:
Lignocaine passes into breast milk although it would be unlikely that the amounts passing to the infant would lead to significant accumulation of the parent drug in the infant. The remote possibility of an idiosyncratic or allergic reaction in the breast fed infant from lignocaine remains to be determined.

DRUG INTERACTIONS:

When amide-type local anaesthetics are given with antiarrhythmics eg, bupivacaine, levobupivacaine, lignocaine or ropivacaine they may increase the risk of myocardial depression. If local anaesthetic containing adrenaline given for epidural or paracervical block during labour the use of an oxytocic drug postpartum may lead to severe hypertension. Although there is no clinical evidence of dangerous interactions between adrenaline-containing local anaesthetics and MAOIs or tricyclic antidepressants, great care should nevertheless be taken to avoid inadvertent intravenous doses of the local anaesthetic preparation. The clearance of lignocaine may be reduced by propranolol and cimetidine. The cardiac depressant effects of lignocaine are additive with those of beta blockers and of other antiarrhythmics. These also occur when lignocaine is given with intravenous phenytoin. The long-term use of phenytoin and other enzyme-inducer may increase dosage requirement of lignocaine; phenytoin and lignocaine may have addition cardiac depressant effect.

Skeletal Muscle Relaxants:
Lignocaine and skeletal muscle relaxants e.g. suxamethonium lead to excessive neuromuscular blockage; therefore this combination must be used with caution.

Structurally-Related Local Anaesthetics:
Lignocaine should be used with caution in patients receiving agents structurally related to local anaesthetics.

Incompatibilities:
Additives may be incompatible although no specific incompatibilities have been reported. The introduction of any additive requires special attention to ensure the incompatibilities do not result. Do not administer unless the solution is clear.

STORAGE:

Store below 30^{O}C. Protect from light. Do not freeze.
Not to be used if solution is not clear and unused portions of solutions from the container should be discarded.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

PACK QUANTITIES:

Available in 10x10ml.

Further information can be obtained from pharmacist, physician or the manufacturer.

Product Registration Holder & Manufactured By:
Kotra Pharma (M) Sdn. Bhd. (90082-V)
No.1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

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