

XYLONOR 3% NORADRENALINE

Composition: For one cartridge of 1.8 ml:

Active ingredients: Lidocaine hydrochloride 54 mg and Noradrenaline bitartrate expressed as base 72 mcg.

Excipient: Isotonic solution (Potassium Metabisulphite, Sodium Edetate, Sodium Chloride, Sodium Hydroxide, Water for Injections) q.s. 1.8 ml

Indications: Local anaesthetic in dental operations which are considered as being difficult and of long duration.

Contraindications: Use of Xylonor 3% Noradrenaline is contraindicated in patients with known hypersensitivity to any of its ingredients and other local anaesthetics of the amide type and should be used cautiously in individuals with a history of allergic reactions. It is contraindicated in patients with hypertension, cardiovascular diseases (especially infarctus, severe shock, impaired cardiac conduction), myasthenia gravis, diabetes, and in patients undergoing treatments with MAOI or tricyclic antidepressants.

Xylonor 3% Noradrenaline is contraindicated when the site of injection is infected or inflamed.

Xylonor 3% Noradrenaline should be used with caution if at all, in geriatric patients and in patients with peripheral vascular diseases, hyperthyroidism, or Graves' disease.

Precautions: The product contains potassium disulphite that may cause allergic- type reactions, including anaphylaxis and life-threatening or less severe asthmatic episodes, in certain susceptible individuals. The overall prevalence of sulfite sensitivity in the general population is unknown but probably low. Such sensitivity appears to occur more frequently in asthmatic than in non asthmatic individuals.

Local anaesthetics should be used only by clinicians who are sufficiently knowledgeable in the diagnosis and management of dose-related toxicity and other acute emergencies that might arise from the type of anaesthetic block to be used. Resuscitative equipment and drugs which may be required for treatment of adverse reactions must be immediately available whenever the drugs are used. Delay in appropriate management of doserelated toxicity, underventilation from any cause, and/or altered sensitivity may lead to the development of acidosis, cardiac arrest, and possibly death. For information on the management of severe CNS or cardiovascular reactions, see CNS and Cardiovascular Effects.

Proper technique is inherent to safe use of local anaesthetics. The drug should be injected slowly and with frequent aspiration to guard against intravascular injection. The injection should be stopped if toxic effects appear.

The drug should be used with caution in severely debilitated patients and in those with liver disease.

Pregnancy: Safe use of local anaesthetics during pregnancy has not been established with respect to adverse effects on foetal development. Careful consideration should be given to this fact before administering these drugs in pregnant women.

Lactation: Safety for use in the nursing mother has not been established. It is not known whether local anaesthetic drugs are excreted in breast milk.

Adverse Effects: Adverse effects of local anaesthetics usually result from high plasma concentrations of the drug caused by inadvertent intravascular injection, excessive dosage, excessive rate of injection, slow metabolic degradation, or injection into highly vascular tissue.

CNS and Cardiovascular Effects: High plasma concentrations of local anaesthetics affect the CNS and cardiovascular system. Generally, high plasma concentrations of the drugs initially produce CNS stimulatory effects manifested by anxiety, apprehension, restlessness, nervousness, disorientation, confusion, dizziness, blurred vision, tremors, twitching, shivering, and seizures, followed by CNS depression manifested by drowsiness, unconsciousness, and respiratory arrest. Nausea, vomiting, chills, miosis, and tinnitus may also occur. In some patients symptoms of CNS stimulation may be transient or absent, and initial CNS effects are depressant in nature.

Adverse cardiovascular effects are depressant and include myocardial depression, bradycardia, cardiac arrhythmias, hypotension, cardiovascular collapse, and cardiac arrest. Although adverse cardiovascular effects usually occur only with high plasma concentrations of local anaesthetic, in rare instances small doses of the drugs used for infiltration have caused cardiovascular collapse. It must be kept in mind that anesthesia itself can affect the cardiovascular and respiratory systems.

Adverse reactions resulting from administration of adrenaline containing solutions include anxiety, palpitation, dizziness, headache, restlessness, tremors, tachycardia, anginal pain, and hypertension. In extreme cases, pulmonary edema and ventricular fibrillation may occur. Noradrenaline is less likely to cause cardiac arrhythmias but instead may cause reflex bradycardia.

In the treatment of CNS and cardiovascular reactions, general physiologic supportive measures such as maintenance of adequate airway, oxygen uptake, and carbon dioxide removal should be instituted immediately. Administration of oxygen and assisted respiration may be sufficient to control anoxia in patients with seizures and avoids the hazards associated with administration of CNS depressant drug. For control of severe seizures, slow IV infusion of diazepam, an ultra-short acting barbiturate, or, if these are not available, a short-acting barbiturate has been recommended. CNS depressants should not be used when asystole, coma, respiratory failure, or hypotension are present. Administration of a short-acting skeletal muscle relaxant (e.g., succinylcholine) in conjunction with artificial respiration has been recommended to block peripheral manifestations of seizures. Some clinicians, however, have questioned the value of skeletal muscle relaxants for treatment of local anaesthetic-induced seizures. In the treatment of cardiovascular collapse, assisted respiration is of utmost importance. IV fluids and vasopressor drugs, preferably those that stimulate the myocardium, have been used to treat hypotension and circulatory collapse. The value of vasopressors in the treatment of cardiogenic shock is controversial, however, cardiac massage should be used if necessary.

Sensitivity Reactions: Hypersensitivity or allergic reactions occur rarely in patients receiving local anaesthetics. These reactions may be manifested by dermatologic reactions, edema, status asthmaticus, or anaphylactoid reactions which may result in death. There is probably no cross-sensitivity between local anaesthetics of the amide type and those of the ester type: however, cross-sensitivity within each type does exist. Although some investigators recommend skin testing in patients with suspected drug sensitivity, the value of this procedure in predicting sensitivity is controversial.

Other adverse effects: A transient burning sensation may occur at the site of injection of local anaesthetics. Rarely prolonged burning, pain, skin discoloration, tissue irritation, swelling, neuritis, neurolysis, tissue necrosis, and sloughing may occur.

Dosage: For ordinary use, one cartridge is sufficient in most cases. Never use more than two cartridges.

Presentation: Box of 50 X 1.8 ml cartridges.

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