Xylopen® 2%

Lidocaine 20 mg and Epinephrine 12.5 mcg/mL

Xylopen®2% (Lidocaine hydrochloride 20 mg and Epinephrine (as bitartrate)12.5mcg Injection)

Indications and Usage

Xylopen® 2% (Lidocaine and Epinephrine) Injection, is indicated for the production of local anesthesia for dental procedures by nerve block or infiltration techniques.

Contraindications

Xylopen® 2% (Lidocaine and Epinephrine) Injection is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type or to any components of the injectable formulations.

Pregnancy Category

Xylopen® 2% (Lidocaine and Epinephrine) Injection is in category B in pregnancy.

Warnings

Dental practitioners who employ local anesthetic agents should be well versed in diagnosis and management of emergencies which may arise from their use. Resuscitative equipment, oxygen and other resuscitative drugs should be available for immediate use.

To minimize the likelihood of intravascular injection, aspiration should be performed before the local anesthetic solution is injected. If blood is aspirated, the needle must be repositioned until no return of blood can be elicited by aspiration. Note, however, that the absence of blood in the syringe does not assure that intravascular injection will be avoided.

Local anesthetic procedures should be used with caution when there is inflammation and/or sepsis in the region of the proposed injection.

Xylopen® 2% (Lidocaine and Epinephrine) Injections contain Sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

Lidocaine, along with other local anesthetics, is capable of producing methemoglobinemia. The clinical signs of methemoglobinemia are cyanosis of the nail beds and lips, fatigue and weakness. If methemoglobinemia does not respond to administration of oxygen, administration of methylene blue intravenously 1-2 mg/kg body weight over a 5 minute period is recommended.

Precautions

Lidocaine should be used with caution in patients with severe shock or heart block. Lidocaine should also be used with caution in patients with impaired cardiovascular function. Local anesthetic solutions containing a vasoconstrictor should be used with caution in areas of the body supplied by end arteries or having otherwise compromised blood supply. Patients with peripheral vascular disease and those with hypertensive vascular disease may exhibit exaggerated vasoconstrictor response. Ischemic injury (such as exfoliating or ulcerating lesions) or necrosis may result. Preparations containing a vasoconstrictor should be used with caution in patients during or following the administration of potent general anesthetic agents, since cardiac arrhythmias may occur under such conditions.

Cardiovascular and respiratory (adequacy of ventilation) vital signs and the patient's state of consciousness should be monitored after each local anesthetic injection. Restlessness, anxiety tinnitus, dizziness, blurred vision, tremors, depression or drowsiness should alert the practitioner to the possibility of central nervous system toxicity. Signs and symptoms of depressed cardiovascular function may commonly result from a vasovagal reaction, particularly if the patient is in an upright position : placing the patient in the recumbent position is recommended when an adverse response is noted after injection of a local anesthetic Vasovagal reactions may elicit a range of clinical manifestations, from pre-syncope (e.g., lightheadedness, pallor, nausea, sweating, visual disturbances, weakness) to brief loss of consciousness (i.e., syncope).

Lidocaine should be used with caution in patients with hepatic disease, since amide-type local anesthetics are metabolized by the liver. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at greater risk of developing toxic plasma concentrations.

Many drugs used during the conduct of anesthesia are considered potential triggering agents for familial malignant hyperthermia. Since it is not known whether amide-type local anesthetics may trigger this

reaction, and since the need for supplemental general anesthesia cannot be predicted in advance, it is suggested that a standard protocol for management should be available. Early unexplained signs of tachycardia, tachypnea, labile blood pressure and metabolic acidosis may precede temperature elevation. Successful outcome is dependent on early diagnosis, prompt discontinuance of the suspected triggering agent (s) and prompt treatment, including oxygen therapy, dantrolene (consult dantrolene sodium intravenous package insert before using) and other supportive measures.

Lidocaine should be used with caution in persons with known drug sensitivities. Patients allergic to para-aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to lidocaine.

Dosage and administration:

Dosage varies with anesthetic procedure, degree of anesthesia required, and physical condition of patient.

Dental anesthesia, infiltration, or conduction block:

Children <12 years: 20-30mg (1-1.5 mL) of Xylopen® 2% (Lidocaine and Epinephrine) maximum: 4.5mg of lidocaine hydrochloride/kg of body weight or 100-150 mg as single dose.

Children ≥12 years and adults: Do not exceed 7 mg/kg body weight up to a maximum range of 300 mg (usual dental practice) to 500 mg (approved product labeling) of lidocaine hydrochloride and 3 mcg (0.003 mg) of epinephrine/kg of body weight or 0.2 mg epinephrine per dental appointment.

The effective anesthetic dose varies with procedure, intensity of anesthesia needed, duration of anesthesia required, and physical condition of patient. Always use the lowest effective dose along with careful aspiration.

Adverse Reactions

Central nervous system (excitation and/or depression, Nervousness, dizziness, blurred vision, or tremors) may occur followed by drowsiness, convulsions, unconsciousness.

Cardiovascular reactions are depressant. (vasovagal reaction) Failure to recognize premonitory signs such as sweating, feeling of faintness, changes in pulse or sensorium (Management consists of placing the patient in the recumbent position and administration of oxygen. Vasoactive drugs such as ephedrine or methoxamine may be administered intravenously).

Allergic reactions are rare and may occur as a result of sensitivity to the local anesthetic and are characterized by cutaneous lesions of delayed onset or urticaria, edema, and other manifestations of allergy.

Storage

Any unused portion of a cartridge should be discarded.

Inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Do not autoclaved.

Use of isopropyl alcohol 91% or ethanol 70% for disinfects the outer surface of cartridges.

Store below 30°C. Protect from light.

Packaging

Each blister contains 5 cartridges (1.8mL) and 10 blisters are in one cartoon.

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