Advisory Leaflet: TAC Alternate Topical Anesthetic Gel
Tetracaine 4%, Phenylephrine 2%, Lidocaine 20%

Maximum recommended adult dose is 0.5gm and 0.2gm in children weighing 40 pounds or more.

Topical/Oral: Do not eat or drink anything until full sensation returns to lips, mouth, and throat. Use caution with heat or cold; Patient will not have accurate hot or cold sensation until full effects of anesthesia have worn off.

WARNING: APPLICATION OF TOPICAL/ORAL ANESTHETICS

Safety and efficacy have not been established. Use of topical or oral anesthetics prior to cosmetic procedures can result in high systemic levels and lead to toxic effects (e.g., arrhythmias, seizures, coma, respiratory depression, and death), particularly when applied in large amounts to cover large areas and/or left on for long periods of time or used with materials, wraps, or dressings to cover the skin after anesthetic application. These practices may increase the degree of systemic absorption and should be avoided. The FDA is recommending consumers consult their healthcare provider for instructions on safe use prior to applying topical anesthetics for medical or cosmetic purposes. Use of products with the lowest amount of anesthetic with the least amount of application possible to relieve pain is also recommended. Dental practitioners and/or clinicians using local anesthetic agents should be well trained in diagnosis and management of emergencies that may arise from the use of these agents. Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use.

ACITVE INGREDIENT: LIDOCAINE HYDROCHLORIDE

PHARMACOLOGY

Blocks both the initiation and conduction of nerve impulses by decreasing the neuronal membrane's permeability to sodium ions, which results in inhibition of depolarization with resultant blockade of conduction

CONTRAINDICATIONS

Hypersensitivity to Lidocaine or any component of the formulation; hypersensitivity to another local anesthetic of the amide type; Adam-Stokes syndrome; severe degrees of SA, AV, or intraventricular heart block (except in patients with a functioning artificial pacemaker).

PRECAUTIONS

Use with extreme caution in elderly patients and children. They may be at an increased risk for adverse effects (cyanosis, tachycardia, anxiety, confusion, dizziness, lethargy, lightheadedness, somnolence, Angioedema, contact dermatitis, depigmentation, edema, Methemoglobinemia, and Hypoxia). Increased absorption in the anterior region of the mouth may occur in these patient populations and the toxic effects of Lidocaine may appear earlier in the elderly and in patients with heart failure, shock, or hepatic disease. Use with extreme caution in patients with hyperthyroidism, bradycardia, partial heart block, myocardial disease or severe arteriosclerosis.

Use caution when application is to broken or inflamed skin. It may lead to increased systemic absorption. Use caution with patients with severe hepatic disease due to diminished ability to metabolize systemically-absorbed Lidocaine.

ACTIVE INGREDIENT: TETRACAINE HYDROCHLORIDE

PHARMACOLOGY

Ester local anesthetic blocks both the initiation and conduction of nerve impulses by decreasing the neuronal membrane's permeability to sodium ions, which results in inhibition of depolarization with resultant blockade of conduction.

CONTRAINDICATIONS

Hypersensitivity to Tetracaine, ester-type anesthetics, amino benzoic acid, or any component of the formulation

PRECAUTIONS

Use with extreme caution and reduce dose in elderly and pediatric patients. Use with caution in any patient with abnormal or decreased levels of plasma esterase, and in patients with hyperthyroidism, and with cardiovascular disease, especially bradychardia, partial heart block, myocardial disease or severe arteriosclerosis. Adverse effects listed are those characteristics of local anesthetics. Systemic adverse effects are generally associated with excessive doses or rapid absorption: Cardiac arrest, hypotension, chills, convulsions, dizziness, drowsiness, nervousness, unconsciousness, urticaria, nausea, vomiting, Methemoglobinemia, tremors, blurred vision, pupil constriction, tinnitus, respiratory arrest, allergic reaction, and anaphylaxis

ACTIVE INGREDIENT: PHENYLEPHRINE HYDROCHLORIDE

PHARMACOLOGY

Phenylephrine is a powerful postsynaptic alpha-receptor stimulant with little effect on the beta-receptors of the heart. The drug is a powerful vasoconstrictor with properties similar to those of norepinephrine but almost completely lacking the actions of the heart. Cardiac irregularities are seen rarely, even with large doses. In contrast to epinephrine and ephedrine, phenylephrine produces longer lasting vasoconstriction, a reflex bradycardia and increases the stroke output, producing no disturbance in the rhythm of the pulse.

CONTRAINDICATIONS

Hypersensitivity to Phenylephrine or any component of the formulation; hypertension; ventricular tachycardia

PRECAUTIONS

Use with extreme caution in elderly patients, patients with cardiovascular disease, including ischemic heart disease, Diabetes mellitus, Hyperthyroidism, in patients with increased intraocular pressure or prostatic hyperplasia. Patients must notify healthcare provider if symptoms do not improve within 7 days or if bleeding occurs. Use with caution since phenylephrine is a sympathomimetic amine which could interact with epinephrine to cause a pressor response. KEY ADVERSE EVENT(S) RELATED TO DENTAL TREATMENT: Tachycardia, palpitations (use vasoconstrictor with caution), and xerostomia (normal salivary flow resumes upon discontinuation). Drug Interaction should be checked and therapy modifications should be considered. **Ref. Lexi-Comp Rev. 11/19/12**