

Topex[®] Topical Anesthetic Metered Spray - 20% Benzocaine

R_x only

USA Metered Spray—2oz/57g
AD31000 Wild Cherry

Canada Metered Spray—2oz/57g
AD31000 Wild Cherry

NPN Number: 02244285
For dental use only.

1. INDICATIONS AND USAGE

Topex Topical Anesthetic Metered Spray is indicated as a topical anesthetic for use on oral mucosa.

2. DOSAGE AND ADMINISTRATION

- ❖ Attach disposable straw to the spray valve.
- ❖ Spray directly on mucosa to achieve topical anesthesia.

3. DOSAGE FORMS AND STRENGTH

Each gram of Topex 20% benzocaine topical anesthetic spray contains between 180-220 mg benzocaine. Each metered spray delivers approximately 6.8 mg of benzocaine.

4. CONTRAINDICATIONS

Should not be used in individuals with a known sensitivity to benzocaine or para-aminobenzoic acid (PABA).

5. WARNINGS AND PRECAUTIONS

Methemoglobinemia

Cases of methemoglobinemia have been reported in association with local anesthetic use. Although all patients are at risk for methemoglobinemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. If local anesthetics must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended.

Signs of methemoglobinemia may occur immediately or may be delayed some hours after exposure, and are characterized by a cyanotic skin discoloration and/or abnormal coloration of the blood. Methemoglobin levels may continue to rise; therefore, immediate treatment is required to avert more serious central nervous system and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death. Discontinue TOPEX Metered Spray and any other oxidizing agents. Depending on the severity of the signs and symptoms, patients may respond to supportive care, i.e., oxygen therapy, hydration. A more severe clinical presentation may require treatment with methylene blue, exchange transfusion, or hyperbaric oxygen

6. DRUG INTERACTIONS

Patients who are administered local anesthetics are at increased risk of developing methemoglobinemia when concurrently exposed to the following drugs, which could include other local anesthetics:

Examples of Drugs Associated with Methemoglobinemia:

Class	Examples
Nitrates/Nitrites	nitric oxide, nitroglycerin, nitroprusside, nitrous oxide
Local anesthetics	articaine, benzocaine, bupivacaine, lidocaine, mepivacaine, prilocaine, procaine, ropivacaine, tetracaine
Antineoplastic agents	cyclophosphamide, flutamide, hydroxyurea, ifosfamide, rasburicase
Antibiotics	dapsone, nitrofurantoin, para-aminosalicylic acid, sulfonamides
Antimalarials	chloroquine, primaquine
Anticonvulsants	Phenobarbital, phenytoin, sodium valproate
Other drugs	acetaminophen, metoclopramide, quinine, sulfasalazine

7. PATIENT COUNSELING INFORMATION

Inform patients that use of local anesthetics may cause methemoglobinemia, a serious condition that must be treated promptly. Advise patients or caregivers to seek immediate medical attention if they or someone in their care experience the following signs or symptoms: pale, gray, or blue colored skin (cyanosis); headache; rapid heart rate; shortness of breath; lightheadedness; or fatigue.

8. OVERDOSAGE

In case of overdose, get medical help or contact a Poison Control Center right away.

9. DESCRIPTION

Flavored 20% benzocaine spray for topical mucosa anesthesia

10. HOW SUPPLIED/STORAGE AND HANDLING

Store between 59°-86°F (15°-30°C).



Manufactured for:
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