

Precaine®

8% Lidocaine, 0.8% Dibucaine Topical Anesthetic Gel

Indications for Use: Oral anesthetic for professional in-office use for the temporary relief of pain during dental procedures, including local anesthetic injections, periodontal curettage, impression taking, scaling, intra-oral radiographs, root planing and prophylaxis. Not intended for home or unsupervised use.

Contraindications: Precaine is contraindicated for patients with known hypersensitivity to lidocaine, dibucaine or PABA compounds.

Warnings:

- Recommended dosage should not be exceeded due to possible side effects.
- Not for use on children 3 and younger, or pregnant or nursing women.
- For topical intraoral use only.
- Do not ingest.
- Keep out of reach of children.

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 and symptoms of methemoglobinemia may occur immediately or may be delayed some hours after exposure and are characterized by a cyanotic skin discoloration and 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 events, including seizures, coma, arrhythmias, and death.

Discontinue Precaine and any other oxidizing agents. Depending on the severity of the symptoms, patients may respond to supportive care, i.e., oxygen therapy, hydration. More severe symptoms may require treatment with methylene blue, exchange transfusion, or hyperbaric oxygen.

Drug Interactions:

Patients that are administered local anesthetics may be at increased risk of developing methemoglobinemia when concurrently exposed to the following oxidizing agents:

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

Precautions:

- Do not use on patients with a history of allergies to local anesthetics such as lidocaine and dibucaine.
- Precaine contains artificial color and artificial flavor; confirm that no known patient allergies exist.
- For professional office use only. Not for home or unsupervised use.
- Protect product from freezing.

Dosage: Not more than one ounce (28g) per patient should be applied during 24 hour period. If more than recommended dose is accidentally swallowed, contact your local Poison Control Center immediately.

Instructions for Use: For best results apply to previously dried oral mucosa with cotton swab or similar applicator.

Removal of excess saliva during application minimizes dilution of the anesthetic and allows maximum penetration.

Care should be taken to prevent patient swallowing Precaine.

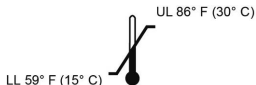
All dispensed Precaine should be discarded after use. Brushes or swabs should not be reused.

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.

For product SDS information please see company website at pascaldental.com or contact Pascal directly.



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