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 stop use and 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.

Hypersensitivity Reactions: Unpredictable adverse reactions (i.e. hypersensitivity, including anaphylaxis) are extremely rare.

Localized allergic reactions may occur after prolonged or repeated use of any aminobenzoate anesthetic. The most common adverse reaction caused by local anesthetics is contact dermatitis characterized by erythema and pruritus that may progress to vesiculation and oozing. This occurs most commonly in patients following prolonged self-medication, which is contraindicated. If rash, urticaria, edema, or other manifestations of allergy develop during use, the drug should be discontinued. To minimize the possibility of a serious allergic reaction, Cetacaine preparations should not be applied for prolonged periods except under continual supervision. Dehydration of the epithelium or an escharotic effect may also result from prolonged contact.

Use in Pregnancy: Safe use of Cetacaine has not been established with respect to possible adverse effects upon fetal development. Therefore, Cetacaine should not be used during early pregnancy, unless in the judgement of a physician, the potential benefits outweigh the unknown hazards. Routine precaution for the use of any topical anesthetic should be observed when Cetacaine is used.

Contraindications

Do not use Cetacaine Spray or Cetacaine Liquid to treat infants or children younger than 2 years.

Cetacaine is not suitable and should never be used for injection. Do not use on the eyes. To avoid excessive systemic absorption, Cetacaine should not be applied to large areas of denuded or inflamed tissue. Cetacaine should not be administered to patients who are hypersensitive to any of its ingredients or to patients known to have cholinesterase deficiencies. Tolerance may vary with the status of the patient.

Cetacaine should not be used under dentures or cotton rolls, as retention of the active ingredients under a denture or cotton roll could possibly cause an escharotic effect. Routine precaution for the use of any topical anesthetic should be observed when using Cetacaine.

Autoclavable Cannula for Cetacaine Spray

- The supplied 4" stainless steel cannula for Cetacaine Spray is specially designed for accessibility and application of Cetacaine, at the required site of pain control. Replacement cannulas are available as a 10-pack (Item # 0205).

Luer-lock Syringes and Microcapillary Delivery Tips for Cetacaine Liquid

- Cetacaine Liquid Syringes and Microcapillary Delivery Tips are supplied with the Cetacaine Liquid Chairside Kit (Item # 0218) and Clinical Kit (Item # 0212). They also can be purchased separately. Syringes are available in packs of 50 (Item # 0219S) or packs of 100 (Item # 0214). Delivery Tips are available in packs of 50 (Item # 0219T) or packs of 100 (Item # 0213).

How Supplied

- Cetacaine Spray, 20 g bottle, including propellant* (Item # 0220, NDC 10223-0201-3) which includes one cannula.
- Cetacaine Spray Single Patient Use, 5 g bottle, including propellant* (Item # 0222, NDC 10223-0201-4) which includes one cannula.
- Cetacaine Liquid Chairside Kit (Item # 0218 NDC 10223-0202-6) which includes one 14 g bottle of Cetacaine Liquid with Luer-lock dispenser cap, 20 syringes and 20 delivery tips.
- Cetacaine Liquid Clinical Kit (Item # 0212, NDC 10223-0202-5) which includes one 30 g bottle of Cetacaine Liquid with Luer-lock dispenser cap, 100 syringes and 100 delivery tips.
- Cetacaine Liquid, 14 g bottle (Item # 0203, NDC 10223-0202-2) with Luer-lock dispenser cap.
- Cetacaine Liquid, 30 g bottle (Item # 0211, NDC 10223-0202-4) with Luer-lock dispenser cap.

***WARNING**

Cetacaine Spray contains CFC-114 and CFC-11, substances which harm public health and environment by destroying ozone in the upper atmosphere. The propellant leak rate of Cetacaine Spray does not meet the USP requirements.

Made in USA

CETYLITE®

Rev. 10 /18

Cetylite Industries, Inc.
Pennsauken, NJ 08110

www.cetylite.com

Cetacaine

Topical Anesthetic

Spray and Liquid

Active ingredients

Benzocaine.....14.0%
Butamben..... 2.0%
Tetracaine Hydrochloride 2.0%

Contains

Benzalkonium Chloride 0.5%
Cetyl Dimethyl Ethyl
Ammonium Bromide..... 0.005%
In a bland, water-soluble base.

Rx Only.

Store at controlled room temperature 20-25°C (68-77°F)

Action

The onset of Cetacaine-produced anesthesia is rapid (approximately 30 seconds) and the duration of anesthesia is typically 30-60 minutes, when used as directed. This effect is due to the rapid onset, but short duration of action of Benzocaine coupled with the slow onset, but extended duration of Tetracaine HCl and bridged by the intermediate action of Butamben.

These agents act by reversibly blocking nerve conduction. Speed and duration of action is determined by the ability of the agent to be absorbed by the mucous membrane and nerve sheath and then to diffuse out, and ultimately be metabolized (primarily by plasma cholinesterases) to inert metabolites which are excreted in the urine.

Indications

Cetacaine is a topical anesthetic indicated for the production of anesthesia of all accessible mucous membrane except the eyes. Cetacaine Spray is indicated for use to control pain or gagging.

Cetacaine in all forms is indicated to control pain and for use for surgical or endoscopic or other procedures in the ear, nose, mouth, pharynx, larynx, trachea, bronchi, and esophagus. It may also be used for vaginal or rectal procedures when feasible.

Dosage and Administration

Cetacaine Spray should be applied for approximately one second or less for normal anesthesia. Only a limited quantity of Cetacaine is required for anesthesia. Spray in excess of two seconds is contraindicated. Each one-second spray contains an average of 200 mg of product, not including propellant.

To apply, insert the cannula firmly onto the protruding plastic stem on the bottle and press the cannula forward to actuate the spray valve. The cannula may be removed and reinserted as many times as required for cleaning, or sterilization, and is autoclavable.

Cetacaine Liquid: Apply 200 mg liquid (approximately 0.2 mL) directly to tissue. Liquid in excess of 400 mg (approximately 0.4 mL) is contraindicated.

To apply, remove and discard the shipping cap from the bottle. Replace it with the supplied Luer-lock cap. Caution: Do not over-tighten. Remove small cap from luer-lock port, retaining it for replacement after use. Port allows for a single dip of a cotton or brush applicator for application directly to accessible mucous membrane. For application into periodontal pockets, Cetylite Luer-lock syringes and Microcapillary Delivery Tips are recommended. Cetylite Syringes are clearly marked in (4) 0.1 mL increments. To fill, attach syringe to port by gently twisting clockwise until secure. Invert and draw desired amount of liquid into the syringe. Remove filled syringe and attach Microcapillary Delivery Tip to the syringe. Tip may be bent to improve access. Apply drop-wise to accessible mucous membrane (such as buccal and lingual sulcus) by slowly depressing the syringe plunger. Discard all applicators after use.

An appropriate pediatric dosage has not been established for Cetacaine Spray or Cetacaine Liquid.

Dosages should be reduced in the debilitated elderly, acutely ill, and very young patients (i.e., children 2 years and older).

Do not use Cetacaine Spray or Cetacaine Liquid to treat infants or children younger than 2 years.

Tissue need not be dried prior to application of Cetacaine. Cetacaine should be applied directly to the site where pain control is required. Anesthesia is produced within one minute with an approximate duration of thirty minutes. Each 200 mg dose of Cetacaine (Spray or Liquid) contains 28 mg of benzocaine, 4 mg of butamben and 4 mg of tetracaine HCl.

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 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 effects, including seizures, coma, arrhythmias, and death. Discontinue Cetacaine 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:

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