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; light-headedness; 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 anesthetic agent. 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 pregnancy, unless in the judgment 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.

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

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 # 0221, NDC 10223-0201-5) 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.
**Action**

The onset of Cetacaine-produced anesthesia is rapid (approximately 30 seconds) and the duration of anesthesia is typically 20-60 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 is 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 cholinesterase) 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 accessible mucous membrane (such as buccal and lingual sulcus) 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.

**WARNINGS AND PRECAUTIONS**

Methemoglobinemia:

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

- Anticonvulsants: phenytoin, sodium valproate, phenobarbital
- Antineoplastic agents: ifosfamide, hydroxyurea
- Antibiotics: para-aminosalicylic acid
- Antimalarials: chloroquine, hydroxychloroquine
- Anticoagulants: sodium phenylbutazone, valproic acid
- Other drugs: ibuprofen, metoclopramide, sulfa drugs (i.e., sulfasalazine), quinine

**Drug Interactions**

Class

Local anesthetics

Antibiotics

Antineoplastics

Anticoagulants

Other drugs