

# Cetacaine<sup>®</sup>

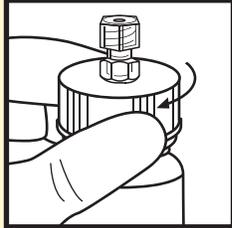
## Topical Anesthetic LIQUID Instructions



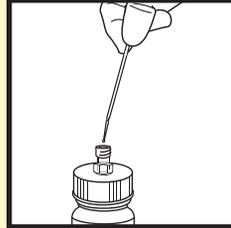
### Instructions for Topical Delivery using a microbrush:



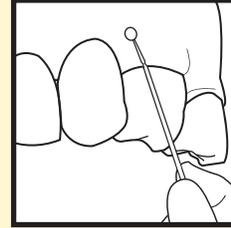
**Fig. 1**  
Remove bottle from box. Remove and discard shipping cap.



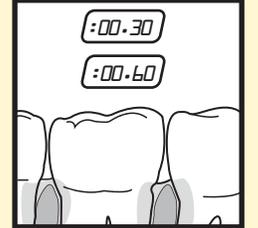
**Fig. 2**  
Securely attach Luer-lock dispensing cap. Remove small cap from Luer-lock port. Retain for replacement after use.



**Fig. 3**  
Luer-lock port allows single dip of microbrush of choice. Replace port cap.



**Fig. 4**  
Apply Cetacaine Liquid drop-wise to accessible mucous membrane.

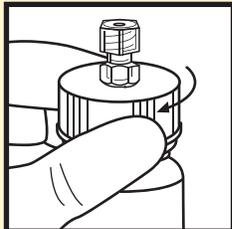


**Fig. 5**  
Wait 30-60 seconds for maximum anesthesia before beginning procedure. The duration of anesthesia is typically 30-60 minutes, when used as directed. Discard microbrush after use.

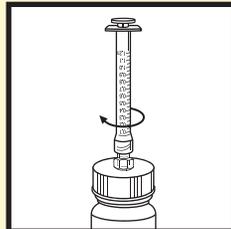
### Instructions for Subgingival Delivery:



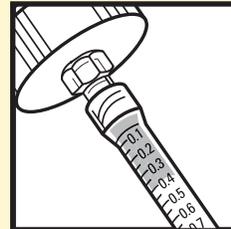
**Fig. 1**  
Remove bottle from box. Remove and discard shipping cap.



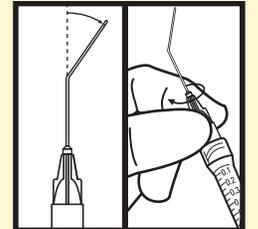
**Fig. 2**  
Securely attach Luer-lock dispensing cap. Remove small cap from Luer-lock port. Retain for replacement after use.



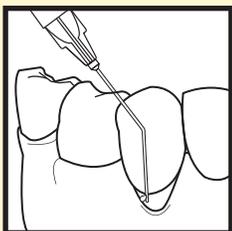
**Fig. 3**  
Lock a 1.2 mL Luer-lock syringe into port. Invert bottle.



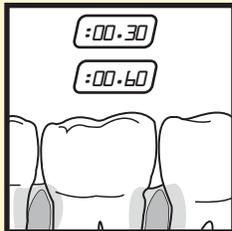
**Fig. 4**  
Draw liquid (0.4 mL maximum). Aspirate accordingly. Remove syringe from port and replace port cap.



**Fig. 5**  
Tip may be bent to improve access. Attach 27 ga Vista-Probe™ Tip to the syringe (or tip of your choice).



**Fig. 6**  
Apply Cetacaine Liquid drop-wise to accessible mucous membrane (such as the buccal and lingual sulcus) by slowly depressing the syringe plunger.



**Fig. 7**  
Wait 30-60 seconds for maximum anesthesia before beginning procedure. The duration of anesthesia is typically 30-60 minutes, when used as directed. Discard syringe and tip after use.

#### Important Safety Information

On rare occasions, methemoglobinemia has been reported in connection with the use of benzocaine-containing products. Care should be used not to exceed the maximum recommended dosage. If a patient becomes cyanotic, treat appropriately to counteract (such as with methylene blue, if medically indicated). 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.

Cetacaine is not right for everyone, including those who are hypersensitive to any of its ingredients or are known to have cholinesterase deficiencies. Please see the brief summary of the Prescribing Information on page six.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.



**CETYLITE**  
INDUSTRIES, INC.  
PIONEER LEADER VISIONARY

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# Cetacaine

## Topical Anesthetic Liquid

### Brief Summary of the Prescribing Information

#### 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.	

#### 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.

#### Indications

Cetacaine is a topical anesthetic indicated for the production of anesthesia of all accessible mucous membrane except the eyes. Cetacaine 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 Liquid Apply 200 mg (approximately 6 – 7 drops or 0.2 cc) with a cotton applicator or directly to tissue. Do not hold the cotton applicator in position for extended periods of time, since local reactions to benzoate topical anesthetics are related to the length of time of application. Liquid in excess of 400 mg (approx. 12 – 14 drops or 0.4 cc) is contraindicated.

\*See Cetacaine Liquid Kit instructions for additional directions for application by Luer-lock syringe and applicator tip.

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

Dosages should be reduced in the debilitated elderly, acutely ill, and very young patients.

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 Liquid contains 28 mg of benzocaine, 4 mg of butamben and 4 mg of tetracaine HCl.

#### Adverse Reactions

**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.

**Precaution:** On rare occasions, methemoglobinemia has been reported in connection with the use of benzocaine-containing products. Care should be used not to exceed the maximum recommended dosage (see Dosage and Administration). If a patient becomes cyanotic, treat appropriately to counteract (such as with methylene blue, if medically indicated).

**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

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.

Rx Only.



Manufactured by:

**CETYLITE  
INDUSTRIES, INC.**  
PIONEER LEADER VISIONARY

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Made in U.S.A.

#### Reorder Information:

##### Cetylite Industries, Inc.

- Cetacaine Liquid Kit, NDC 10223-0202-3, Item No. 0210
- Cetacaine Liquid (14g) with Luer-lock Dispenser Cap  
NDC 10223-0202-2, Item No. 0203
- Cetacaine Liquid (30g) with Luer-lock Dispenser Cap  
NDC 10223-0202-4, Item No. 0211

##### Vista™ Dental Products

- Vista™ 1.2 mL Luer-lock syringes, 100 per box,  
Item No. 316002
- Vista-Probe™ Needle Tips, 27 ga, 20 per cup,  
Item No. 315127