

Cetacaine®

Topical Anesthetic Gel

(Benzocaine 14.0 %, Butamben 2.0 %, Tetracaine Hydrochloride 2.0 %)



Cetacaine® Topical Anesthetic Gel is a fast-acting, long-lasting prescription topical anesthetic that can be applied directly to the required site. Cetacaine is primarily used to control pain and ease discomfort at the site where it is applied.

The new pump-top jar controls the amount of Cetacaine dispensed. The protective lid easily comes off and on to keep the surface clean and intact.

Please see the Brief Summary of the Prescribing Information on the reverse side. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Cetacaine Gel is indicated for anesthesia of accessible mucous membrane except the eyes.

Rx only.



Conveniently dispensed by finger tip pressure on pump-top jar.

Description	Cetacaine Topical Anesthetic Gel
Size	32g
Item No.	8150361

Key Features & Benefits

- Onset of anesthesia is within 30-60 seconds and duration is typically 30 - 60 minutes
- Controls pain and eases discomfort at the site where it is applied
- Lubricating qualities
- Cost-efficient
- Applies evenly and consistently
- Reacts with body temperature to melt and absorb quickly into tissue

Important Safety Information

- On rare occasions, methemoglobinemia has been reported in connection with the use of benzocaine-containing products. If a patient becomes cyanotic, treat appropriately to counteract (such as with methylene blue, if medically indicated).
- Care should be used not to exceed the maximum recommended dosage.
- 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 may not be right for everyone including those who are hypersensitive to any of its ingredients or are known to have cholinesterase deficiencies.



DARBY DENTAL SUPPLY, LLC

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800.645.2310
or Visit darby.com**

Cetacaine

Topical Anesthetic Gel

Tissue need not be dried prior to application of Cetacaine Topical Anesthetic Gel. Cetacaine Topical Anesthetic Gel 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 Topical Anesthetic Gel contains 28 mg of benzocaine, 4 mg of butamben and 4 mg of tetracaine HCL.

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

Only a limited quantity of Cetacaine Topical Anesthetic Gel is required for anesthesia.

Dispense 200 mg of gel (a bead approximately 1/4 to 1/2 inches long) by gently depressing the pump. Dispensing a bead of gel in excess of 400 mg is contraindicated. Spread thinly and evenly over the desired area using a cotton swab.

In the event that a Cetacaine Gel pump jar won't dispense, attempt the following:

1. Using a gloved hand, depress the pump fully using the thumb and middle finger.
2. While depressed, cover the center orifice with the index finger.
3. With the orifice still covered, slowly allow the pump to return to its original starting position.
4. Repeat until Cetacaine Gel is dispensed (usually about 3-4 repeated attempts).

An appropriate pediatric dosage has not been established for Cetacaine Topical Anesthetic Gel.

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

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.



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