

CETACAINE ANESTHETIC- benzocaine, butamben, and tetracaine hydrochloride solution
Cetylite Industries, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Cetacaine
Topical Anesthetic

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. 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.

It is believed that all of 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. Average expulsion rate of residue from spray, at normal temperatures, is 200 mg per second.

To apply, insert the Jetco cannula (J-4) 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 (approximately 0.2 mL) 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 (approximately 0.4 mL) is contraindicated.

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

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

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

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 (Spray residue, Liquid or Gel) 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.

Jetco® Cannula for Cetacaine Spray

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

How Supplied

- Cetacaine Spray, 56 g bottle, including propellant¹ (Item # 0201, NDC 10223-0201-1) which includes one J-4 cannula.
- Cetacaine Gel, 32 g pump jar, (Item # 0217, NDC 10223-0217-3)
- 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)
- Cetacaine Liquid, 30 g bottle (Item # 0211, NDC 10223-0202-4)

¹ WARNING

Cetacaine Spray contains CFC-114 and CFC-11, substances which harm public health and environment by destroying ozone in the upper atmosphere.

Rx Only.

Made in U.S.A.

Cetylite Industries, Inc.

Pennsauken, NJ 08110

www.cetacaine.com

Rev. 4/13

PRINCIPAL DISPLAY PANEL - 30 g Bottle Box

NDC 10223-0202-4

Item No. 0211

Cetacaine®

Topical Anesthetic

LIQUID

With Luer-lock

Dispenser Cap

30g

Control Pain

Effective Only on

Mucous Membrane

CETYLITE®



CETACAINE ANESTHETIC

benzocaine, butamben, and tetracaine hydrochloride solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10223-0202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	0.028 g in 0.2 g
Butamben (UNII: EFW857872Q) (Butamben - UNII:EFW857872Q)	Butamben	0.004 g in 0.2 g
Tetracaine Hydrochloride (UNII: 5NF5D4OPCI) (Tetracaine - UNII:0619F35CGV)	Tetracaine Hydrochloride	0.004 g in 0.2 g

Inactive Ingredients

Ingredient Name	Strength
Dipropylene glycol (UNII: E107L85C40)	
Saccharin (UNII: FST467XS7D)	
Benzalkonium chloride (UNII: F5UM2KM3W7)	
Mecetronium Bromide (UNII: 7ZLNQ7FIO9K)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BANANA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10223-0202-2	1 in 1 BOX	01/01/1960	
1		14 g in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
2	NDC:10223-0202-4	1 in 1 BOX	01/01/1960	
2		30 g in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
3	NDC:10223-0202-5	1 in 1 KIT	01/01/1960	
3		30 g in 1 BOTTLE, GLASS; Type 1: Convenience Kit of Co-Package		
4	NDC:10223-0202-6	1 in 1 KIT	01/01/1960	
4		14 g in 1 BOTTLE, GLASS; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1960	

Labeler - Cetylite Industries, Inc. (001283704)

Establishment

Name	Address	ID/FEI	Business Operations
Cetylite Industries, Inc.		001283704	MANUFACTURE(10223-0202) , ANALYSIS(10223-0202) , LABEL(10223-0202) , PACK(10223-0202)