CETACAINE TOPICAL ANESTHETIC- benzocaine, butamben, and tetracaine hydrochloride gel
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 GEL

Rx Only

Active Ingredients:

Benzocaine	14.0%
Butamben	2.0%
Tetracaine Hydrochloride	2.0%

in a base consisting of polyethylene glycol, purified water, saccharin, cetyldimethylethylammonium bromide, flavoring and color

Action

The onset of Cetacaine Topical Anesthetic Gel 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 Topical Anesthetic Gel is a topical anesthetic indicated for the production of anesthesia of all accessible mucous membrane except the eyes. Cetacaine Topical Anesthetic Gel is indicated for use to control pain and for use for surgical or endoscopic procedures, or other procedures in the ear, nose, mouth, pharynx, larynx, trachea, bronchi, and esophagus. It may also be used for vaginal or rectal procedures where 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 unlikely 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.

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

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 in approximately 30 seconds with an approximate duration of thirty to sixty 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.

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

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 Topical Anesthetic Gel 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 Topical Anesthetic Gel has not been established with respect to possible adverse effects upon fetal development. Therefore, Cetacaine Topical Anesthetic Gel 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 Topical Anesthetic Gel is used.

Contraindications

Do not use Cetacaine Gel 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 Topical Anesthetic Gel should not be applied to large areas of denuded or inflamed tissue. Cetacaine Topical Anesthetic Gel 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 status of the patient.

Cetacaine Topical Anesthetic Gel should not be used under dentures or cotton rolls, as retention of the active gel 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 Topical Anesthetic Gel.

How Supplied

Cetacaine Topical Anesthetic Gel (Strawberry), 32 g jar
NDC 10223-0217-3
Item# 0217

Cetacaine Topical Anesthetic Gel (Mint), 32 g jar
NDC 10223-0221-1
Item# 0221

Made in USA

Cetylite Industries, Inc.
Pennsauken, NJ 08110
www.cetacaine.com

Rev. 10/18

PRINCIPAL DISPLAY PANEL - 32 g Jar Box - Strawberry

NDC 10223-0217-3
Item# 0217

Cetacaine®
Topical Anesthetic GEL

(14% Benzocaine, 2% Butamben, and 2% Tetracaine Hydrochloride)

Indicated for anesthesia of all
accessible mucous membrane
except the eyes.

Strawberry Flavor

Net Contents: 32 g

NDC 10223-0217-3 Item# 0217

Cetacaine®

Topical Anesthetic GEL

(14% Benzocaine, 2% Butamben, and 2% Tetracaine Hydrochloride)

Indicated for anesthesia of all accessible mucous membrane except the eyes.

Strawberry Flavor

Net Contents: 32 g

Rev. 02/17

Ingredients: Benzocaine 14%, butamben 2%, tetracaine hydrochloride 2%, in a base consisting of polyethylene glycol, purified water, saccharin, cetyldimethylethylammonium bromide, flavoring and color

Rx Only.

Caution: Do not use in eyes. Keep out of the reach of children.

HIDDEN AREA

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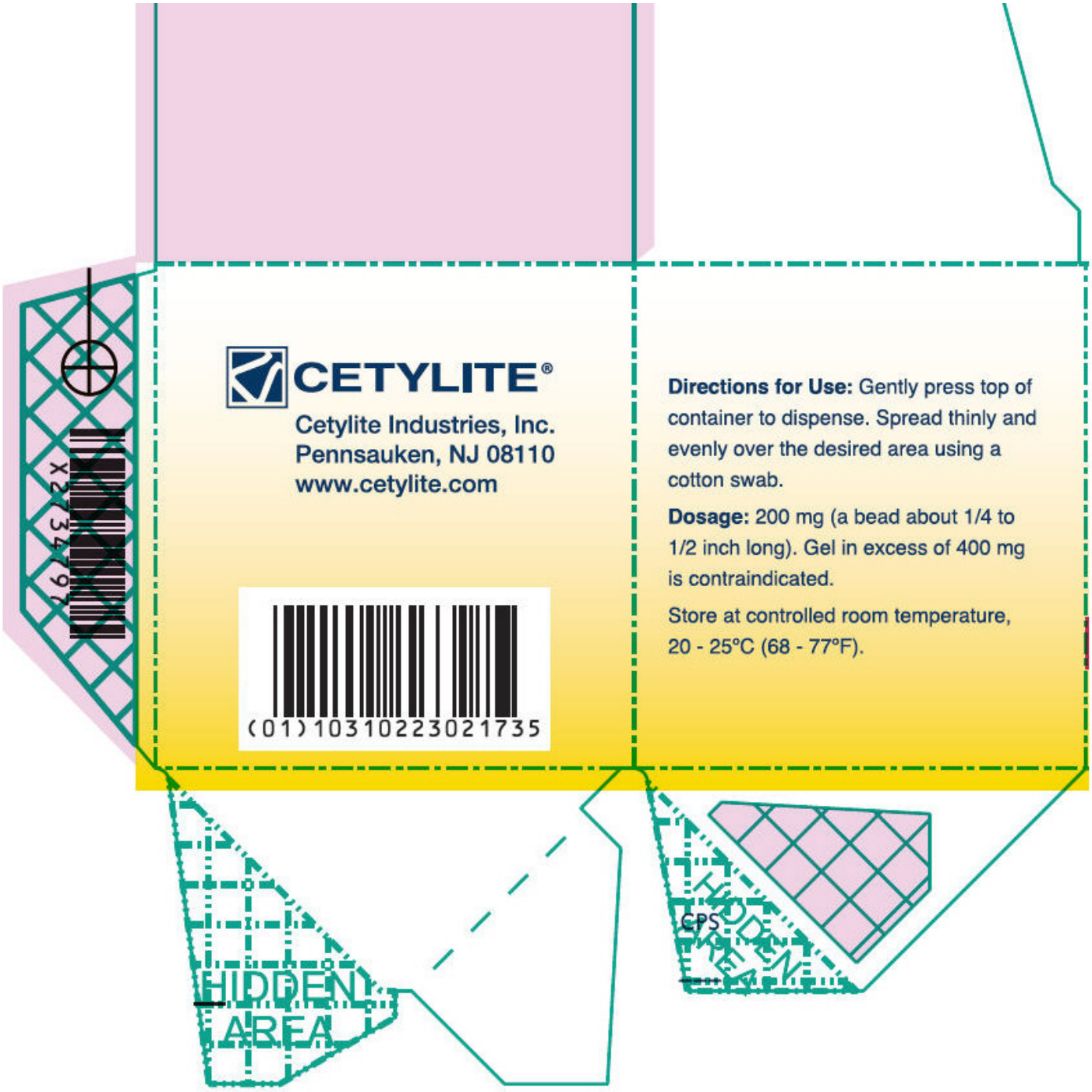

PRINCIPAL DISPLAY PANEL - 32 g Jar Box - Mint

NDC 10223-0221-1
Item# 0221

Cetacaine®
Topical Anesthetic GEL

(14% Benzocaine, 2% Butamben, and 2% Tetracaine Hydrochloride)

Indicated for anesthesia of all accessible mucous membrane except the eyes.

Cool Mint Flavor

Net Contents: 32 g

Rev. 02/17

NDC 10223-0221-1 Item# 0221

Cetacaine®

Topical Anesthetic GEL

(14% Benzocaine, 2% Butamben, and 2% Tetracaine Hydrochloride)

Indicated for anesthesia of all accessible mucous membrane except the eyes.

Cool Mint Flavor

Net Contents: 32 g

Rev. 02/17

Ingredients: Benzocaine 14%, butamben 2%, tetracaine hydrochloride 2%, in a base consisting of polyethylene glycol, purified water, saccharin, cetyldimethylethylammonium bromide, flavoring and color

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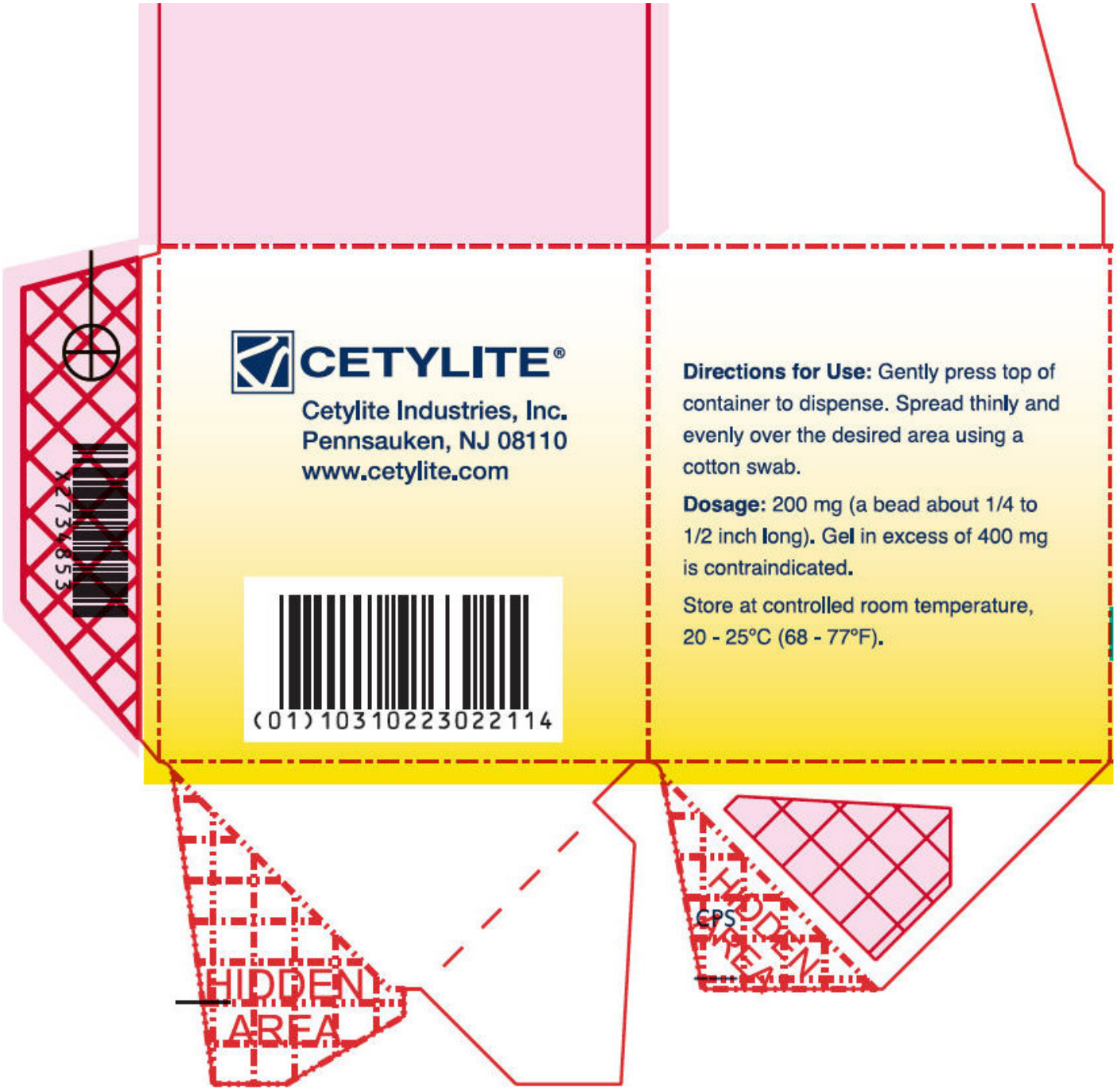

CETACAINE TOPICAL ANESTHETIC

benzocaine, butamben, and tetracaine hydrochloride gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:10223-0217
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
Polyethylene Glycol, Unspecified (UNII: 3WQ0SDW1A)	
Saccharin (UNII: FST467XS7D)	
Benzalkonium chloride (UNII: F5UM2KM3W7)	
Mecetronium bromide (UNII: 7ZNQ7FIO9K)	
Water (UNII: 059QF0KO0R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	STRAWBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10223-0217-3	1 in 1 BOX	01/01/1960	
1		32 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

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

CETACAINE TOPICAL ANESTHETIC

benzocaine, butamben, and tetracaine hydrochloride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:10223-0221
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
Polyethylene Glycol, Unspecified (UNII: 3WQ0SDW1A)	
Saccharin (UNII: FST467XS7D)	
Benzalkonium chloride (UNII: F5UM2KM3W7)	
Mecetronium bromide (UNII: 7ZNQ7FIO9K)	
Water (UNII: 059QF0KO0R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10223-0221-1	1 in 1 BOX	01/01/1960	
1		32 g in 1 JAR; Type 0: Not a Combination Product		

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(10223-0217, 10223-0221) , ANALYSIS(10223-0217, 10223-0221) , LABEL(10223-0217, 10223-0221) , PACK(10223-0217, 10223-0221)