

GELATO TOPICAL ANESTHETIC- benzocaine spray, metered
Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak
Products Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient

Benzocaine 20%

Purpose

Oral Anesthetic

Uses

- For the temporary relief of occasional minor irritation and pain associated with canker sores and minor dental procedures.
- For Professional Use Only.

Warnings

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in the blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy Alert: Do not use on patients with a history of allergies to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.

Flammable. Do not use near fire or flame. Avoid smoking during use.

Do not use

- for teething
- in children under 2 years of age

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Avoid spraying in eyes.

Directions

Apply only amount needed to the oral mucosa to prevent or relieve pain.

- Children under 2 years of age: do not use

Other information

Store at room temperature. Do not store above 120°F (49°C). Dispose of in a manner consistent with local regulations.

Inactive Ingredients

Ethyl Alcohol, Flavor, Polyethylene Glycol, Sodium Saccharin, Hydrocarbon Propellant (Isobutane and propane).

Questions or comments?

1-800-333-3131

Benzocaine 20%

Metered Spray
Topical Anesthetic



Gelato
Topical Anesthetic
Metered Spray

Benzocaine 20%

Peppermint

Dosage: Single Spray 50 mg
Important: Read directions for proper use.

Net Wt. 2 oz. (57g)

Drug Facts

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Benzocaine 20%	Oral Anesthetic

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Gelato
Topical Anesthetic
Metered Spray

Benzocaine 20%

Peppermint

Dosage: Single Spray 50 mg
Important: Read directions for proper use.

Net Wt. 2 oz. (57g)

MANUFACTURED BY:
keystone
industries
480 S. Democrat Rd.
Gibbstown, NJ 08027 USA
keystoneindustries.com
1-800-333-3131

REF 03-01519



MADE IN USA
99088600 Rev 06/18

Drug Facts		Drug Facts (continued)	
Active ingredient Benzocaine 20%	Purpose Oral Anesthetic	Do not use	 <p>Topical Anesthetic Metered Spray</p> <p>Benzocaine 20% Peppermint</p> <p>Dosage: Single Spray 50 mg Important: Read directions for proper use.</p> <p>Re-order#: 03-01519</p>  <p>03-01519</p>
Uses	<ul style="list-style-type: none"> For the temporary relief of occasional minor irritation and pain associated with canker sores and minor dental procedures. For Professional Use Only. 	<ul style="list-style-type: none"> for teething in children under 2 years of age 	
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		Inactive ingredients	
		Ethyl Alcohol, Flavor, Polyethylene Glycol, Sodium Saccharin, Hydrocarbon Propellant (isobutane and propane).	
		Questions or comments?	
		1-800-333-3131	
		<p>MANUFACTURED BY:  480 S. Democrat Rd. Gibbstown, NJ 08027 USA keystoneindustries.com 1-800-333-3131</p>	
		MADE IN USA	Net Wt. 2 oz. (57g)
		99088504 Rev 09/2018	

GELATO TOPICAL ANESTHETIC

benzocaine spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68400-323
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	11.4 g in 57 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ALCOHOL (UNII: 3K9958V90M)	
ISOBUTANE (UNII: BXR49TP611)	
PROPANE (UNII: T75W9911L6)	

Product Characteristics

Color	white (Clear)	Score	
Shape		Size	

Flavor	PEPPERMINT		Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68400-323-35	57 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/01/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	07/29/2013		

Labeler - Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc (014769301)

Establishment

Name	Address	ID/FEI	Business Operations
Keystone Industries		014769301	manufacture(68400-323) , label(68400-323)

Revised: 1/2022

Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc