

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

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

New width 4.5

Drug Facts Active ingredient Benzocaine 20% Oral Anesthetic Purpose Oral Anesthetic		Drug Facts (continued) 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.	<p>Topical Anesthetic Metered Spray Anestésico tópico en Spray</p> <p>Benzocaine 20% Benzocaina 20%</p> <p>Peppermint Menta</p> <p>Dosage: Single Spray 50 mg Dosificación: Por Pulsera 50 mg</p> <p>Important: Read directions for proper use. Importante: lee las instrucciones para un uso adecuado.</p> <p>REF 03-01519</p> <p>03-01519</p> <p>Net Wt./Peso Neto 2 oz. (57g)</p>
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Questions or comments? 1-800-333-3131 Manufactured by/Fabricado por keystone 480 S. Democrat Rd. Gibbstown, NJ 08027 USA keystoneindustries.com 1-800-333-3131		99088505 Rev 1 11/2021 	

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 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	09/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	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: 4/2024

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