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

Active Ingredients

Benzocaine 200mg (in each g)

Purpose:

Oral Anesthetic

Use

For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

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.

Do not use

- for more than 7 days unless directed by a physician. If sore mouth symptoms do not improve in 7 days; irritation, pain or redness persists or worsens; or if swelling, rash or fever develops, see your physician promptly.
- for teething
- in children under 2 years of age

When using this product Avoid contact with eyes. If contact occurs, flush with water.

Do not exceed recommended dosage. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away. **If pregnant or breast feeding,** ask a physician before use.

Directions

- Apply only amount needed to the oral mucosa to prevent or relieve pain.
- children under 2 years of age: do not use

Keep out of reach of children.

Other Information:

Store at 59°-86°F (15°-30°C). Protect from freezing.

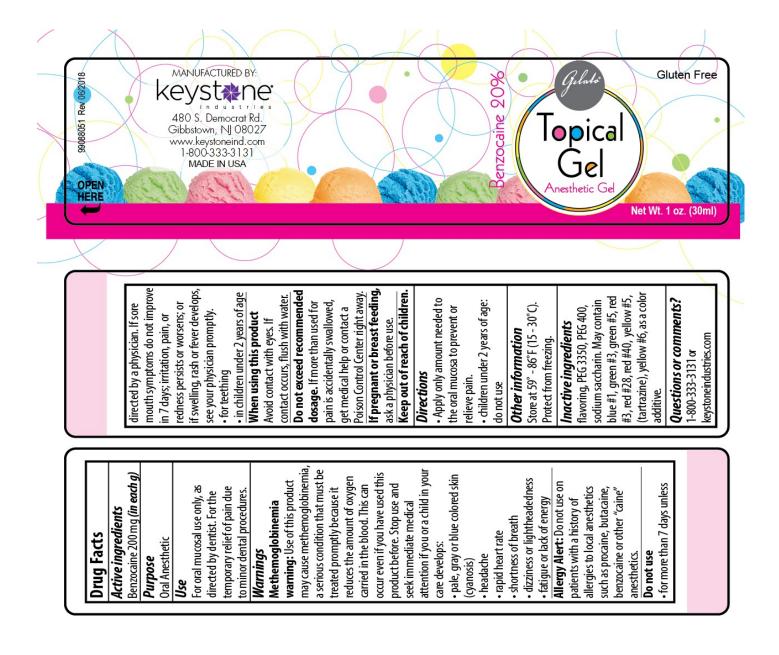
Inactive Ingredients:

Flavoring, PEG 3350, PEG 400, sodium saccharin. May contain blue #1, green #3, green #5, red #3, red #28, red #40, yellow#5 (tartrazine), yellow #6, as a color additive.

Questions or comments?

1-800-333-3131 or

keystoneindustries.com



GELATO TOPICAL AN					
	ESTRETIC				
benzocaine gel					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code	(Source)	NDC:	68400-359
Route of Administration	DENTAL				
Active Ingredient/Active	Moiety				
Ingredient Name Basis of Stre			Basis of Stren	gth	Strength
BENZOCAINE (UNII: U3RSY48JW5)	(BENZOCAINE - UNII:U3RSY	48JW5)	BENZOCAINE		200 mg in 1 g
Inactive Ingredients					
	Ingredient Name				Strength

POLYETHYLENI	E GLYCOL 3350 (UNII: G2M7P15E5P)			
POLYETHYLENI	E GLYCOL 400 (UNII: B697894SGQ)			
SACCHARIN SO	DIUM (UNII: SB8ZUX40TY)			
FD&C YELLOW	NO. 5 (UNII: 1753WB2F1M)			
FD&C YELLOW	NO. 6 (UNII: H77VEI93A8)			
FD&C RED NO.	3 (UNII: PN2ZH5LOQY)			
FD&C RED NO. 40 (UNII: WZ B9127XOA)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)				
D&C GREEN NO). 5 (UNII: 8J6RDU8L9X)			
D&C RED NO. 2	28 (UNII: 767IP0Y5NH)			
Product Cha	aracteristics			
Color	white (DYE FREE)	Score		
Shape		Size		
F 1	PINEAPPLE (PINA COLADA)	Imprint Code		
Flavor				

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68400-359- 30	30 g in 1 JAR; Type 0: Not a Combination Product	06/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	07/01/2013	

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(68400-359) , label(68400-359)	
Revised: 12/2023	Mycone Dei	ntal Supply Co.	, Inc DBA Keystone Industries and Deepak Products Inc	