QUALA TOPICAL ANESTHETIC GEL- benzocaine gel 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 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

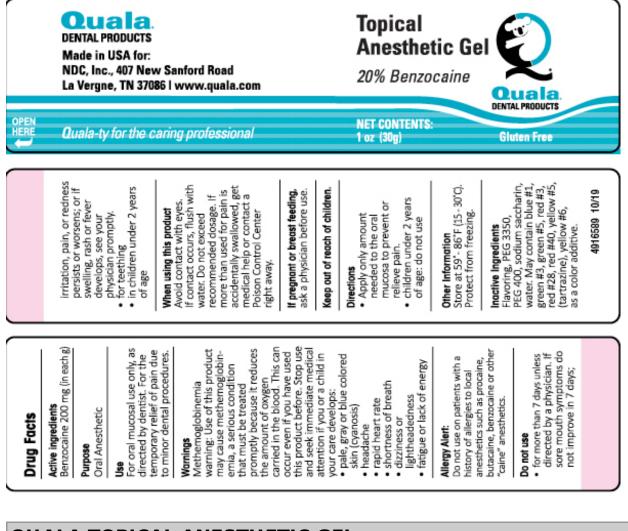
Keep out of reach of children.

Other Information

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

Inactive Ingredients

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



QUALA TOPICAL ANESTHETIC GEL

benzocaine gel

Product Inform							
Product Type		HUMAN OTC DRUG	Item Coo	le (Source)	NDC:68400-475		
Route of Administ	tration	DENTAL					
Active Ingredie	nt/Acti	ve Moiety					
	Ing	redient Name		Basis of Stre	ngth	Strength	
BENZOCAINE (UNII: U	J3RSY48J	W5) (BENZOCAINE - UNII:U3RS	Y48JW5)	BENZOCAINE	200 mg in 1 g		
Inactive Ingred	ients						
		Ingredient Name			St	rength	
		50 (UNII: G2M7P15E5P)					
		(UNII: B697894SGQ)					
SACCHARIN SODIUM	-						
FD&C YELLOW NO. FD&C YELLOW NO.							
FD&C FELLOW NO. FD&C RED NO. 3 (UI							
FD&C RED NO. 3 (0) FD&C RED NO. 40 (0							
FD&C BLUE NO. 1 (
FD&C GREEN NO. 3							
D&C RED NO. 28 (UI							
D&C GREEN NO. 5	JNII: 8J6R	DU8L9X)					
WATER (UNII: 059QFC	KO0R)						
Product Charac	teristi	cs					
Color		pink	Score	<u> </u>			
Shape		Size					
Flavor	BUBBLE GUM Imprint Code						
Contains							
Packaging							
# Item Code	I	Package Description	Ma	arketing Start Date		ting End ate	
	30 g in 1 j Product	JAR; Type 0: Not a Combinatio	n 02/03	/2022			
Marketing Ir	nform	ation					
Marketing Ir Marketing Category		ation lication Number or Monc Citation	graph	Marketing Start Date		eting End Date	
		lication Number or Mono Citation				eting End Date	

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

			stablishment
ID/FEI Business	ID/FEI	Address	Name
014769301 manufacture(68400-475) , lab	014769301	01	eystone Industries
014769301 manufacture(68400-475) , lab	014769301	01	eystone Industries

Revised: 2/2022 Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc.