# QUALA TOPICAL ANESTHETIC GEL- benzocaine gel National Distribution & Contracting, 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.

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# **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 dos age.** 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

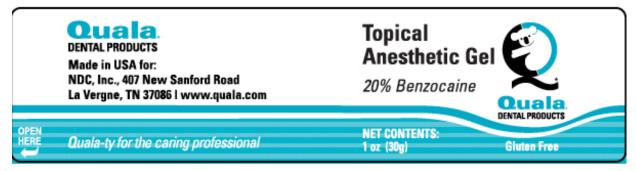
# Keep out of reach of children.

#### 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.



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# **Drug Facts**

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**QUALA TOPICAL ANESTHETIC GEL** 

benzocaine gel

#### **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:43128-031 Route of Administration DENTAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5)	BENZOCAINE	200 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)		
D&C RED NO. 28 (UNII: 767IP0 Y5NH)		
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics			
Color	green	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

ı	Packaging					
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
ı	1 NDC:43128-031-30	30 g in 1 JAR; Type 0: Not a Combination Product	10/01/2019			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	10/01/2019		

# **Labeler** - National Distribution & Contracting, Inc (009831413)

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