

QUALA TOPICAL ANESTHETIC GEL- 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, 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
DENTAL PRODUCTS

Made in USA for:
NDC, Inc., 407 New Sanford Road
La Vergne, TN 37086 | www.quala.com

Topical Anesthetic Gel

20% Benzocaine



Quala
DENTAL PRODUCTS

OPEN HERE

Quala-ty for the caring professional

NET CONTENTS:
1 oz (30g)

Gluten Free

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.

Keep out of reach of children.

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 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.

4916589 10/19

Drug Facts

Active ingredients
Benzocaine 200 mg (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;

QUALA TOPICAL ANESTHETIC GEL

benzocaine gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68400-478

Route of Administration	DENTAL
--------------------------------	--------

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
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: 767IP0Y5NH)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
WATER (UNII: 059QF0KOOR)	

Product Characteristics			
Color	yellow	Score	
Shape		Size	
Flavor	PINEAPPLE (Pina Colada)	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68400-478-30	30 g in 1 JAR; Type 0: Not a Combination Product	02/03/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	02/03/2022	

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

Establishment

Name	Address	ID/FEI	Business Operations
Keystone Industries		014769301	label(68400-478) , manufacture(68400-478)

Revised: 1/2025

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