

**TOPICAL ANESTHETIC- benzocaine gel
NDC, Inc.**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

**Topical Anesthetic Gel -
20% Benzocaine**

Gel – 1oz/34g

2731001 Cherry

2731002 Mint

2731004 Pina Colada

2731005 Bubble Gum

2731006 Strawberry

2731007 Raspberry

For dental use only

Rx only

1. INDICATIONS AND USAGE

Indicated as a topical anesthetic for use on oral mucosa prior to local anesthetic injections, scaling and prophylaxis. Also useful to relieve discomfort associated with taking impressions and intra- oral radiographs.

2. DOSAGE AND ADMINISTRATION

- Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the bottle.
- Tightly re-cap the jar after each use.

3. DOSAGE FORMS AND STRENGTH

Each gram of 20% Benzocaine Gel contains between 180-220 mg benzocaine in a flavored base.

4. CONTRAINDICATIONS

Should not be used with individuals with a known sensitivity to benzocaine or PABA.

5. WARNINGS AND PRECAUTIONS

METHEMOGLOBINEMIA WARNING

Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient 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

- ☐ Not for use in children under 2 years of age
- ☐ Keep out of reach of children
- ☐ For professional dental use only
- ☐ Take care not to contaminate the bottle by reintroducing a used cotton applicator into the bottle

6. OVERDOSAGE

In case of overdose, get medical help or contact a Poison Control Center right away.

7. DESCRIPTION

Flavored 20% benzocaine gel for topical mucosa anesthesia

8. HOW SUPPLIED/STORAGE AND HANDLING

20% benzocaine gel is supplied in multiple use containers

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

For more information call NDC at 1-800-929-4232

Manufactured for NDC Nashville, TN 37217

Made in the USA

2731001DF, R1-120116

PRINCIPAL DISPLAY PANEL - 34 g Jar Label - Cherry

Topical Anesthetic Gel

(20% Benzocaine)

For Professional Use Only

Cherry

Q®

Quala

DENTAL PRODUCTS

2731001

*Quala-ty for the
caring professional*

INGREDIENTS: Each gram of Quala 20% benzocaine gel contains between 180-220 mg benzocaine U.S.P., in a water soluble base of PEG 3350 U.S.P., PEG 400 U.S.P., flavor, sodium saccharin U.S.P., and FD&C Red #40.

USUAL DOSAGE: For oral mucosal use only as directed by dentist.

WARNING: Keep out of reach of children. Do not use on people with known allergies to benzocaine and PABA compounds.

Store at controlled room temperature: 59-86°F (15-30°C).

2731021LA
R# 9/22/08

For more information call ADC at 1-800-929-4ADC

Manufactured for  Nashville, TN 37217

MADE IN U.S.A.

Topical Anesthetic Gel

(20% Benzocaine)

Cherry

For Professional Use Only



2731001

Quala-ty for the
caring professional



+D02327310011V

PRINCIPAL DISPLAY PANEL - 34 g Jar Label - Mint

Topical Anesthetic Gel

(20% Benzocaine)

For Professional Use Only

Mint

Q®

Quala

DENTAL PRODUCTS

2731002

*Quala-ty for the
caring professional*

INGREDIENTS: Each gram of Quala 20% benzocaine gel contains between 180-220 mg benzocaine U.S.P., in a water soluble base of PEG 3350 U.S.P., PEG 400 U.S.P., flavor, sodium saccharin U.S.P., and FD&C Green #5.


USUAL DOSAGE: For oral mucosal use only as directed by dentist.

WARNING: Keep out of reach of children. Do not use on people with known allergies to benzocaine and PABA compounds.

Store at controlled room temperature: 59-86°F (15-30°C).

2731021LA
R# 9/22/08

For more information call ADC at 1-800-929-4ADC

Manufactured for  Nashville, TN 37217

MADE IN U.S.A.

Topical Anesthetic Gel

(20% Benzocaine)

Mint

For Professional Use Only



2731002

Quala-ty for the
caring professional



+D02327310021W

PRINCIPAL DISPLAY PANEL - 34 g Jar Label - Piña Colada

Topical Anesthetic Gel

(20% Benzocaine)

For Professional Use Only

Piña Colada

Q®

Quala

DENTAL PRODUCTS

2731004

*Quala-ty for the
caring professional*

INGREDIENTS: Each gram of Quala 20% benzocaine gel contains between 180-220 mg benzocaine U.S.P., in a water soluble base of PEG 3350 U.S.P., PEG 400 U.S.P., flavor, sodium saccharin U.S.P.

USUAL DOSAGE: For oral mucosal use only as directed by dentist.

WARNING: Keep out of reach of children. Do not use on people with known allergies to benzocaine and PABA compounds.

Store at controlled room temperature: 59-86°F (15-30°C).

2731004A
1R 9/22/08

For more information call ADC at 1-800-929-4ADC

Manufactured for  Nashville, TN 37217

MADE IN U.S.A.

Topical Anesthetic Gel

(20% Benzocaine)

Piña Colada

For Professional Use Only



2731004

Quala-ty for the
caring professional



PRINCIPAL DISPLAY PANEL - 34 g Jar Label - Bubble Gum

Topical Anesthetic Gel

(20% Benzocaine)

For Professional Use Only

Bubble Gum

Q®

Quala

DENTAL PRODUCTS

2731005

*Quala-ty for the
caring professional*

INGREDIENTS: Each gram of Quala 20% benzocaine gel contains between 180-220 mg benzocaine U.S.P., in a water soluble base of PEG 3350 U.S.P., PEG 400 U.S.P., flavor, sodium saccharin U.S.P., and FD&C Red #28.


USUAL DOSAGE: For oral mucosal use only as directed by dentist.

WARNING: Keep out of reach of children. Do not use on people with known allergies to benzocaine and PABA compounds.

Store at controlled room temperature: 59-86°F (15-30°C).

2731005A
1R 9/22/08

For more information call ADC at 1-800-929-4ADC

Manufactured for  Nashville, TN 37217

MADE IN U.S.A.

Topical Anesthetic Gel

(20% Benzocaine)

Bubble Gum

For Professional Use Only



2731005

Quala-ty for the
caring professional



PRINCIPAL DISPLAY PANEL - 34 g Jar Label - Strawberry

Topical Anesthetic Gel

(20% Benzocaine)

For Professional Use Only

Strawberry

Q®

Quala

DENTAL PRODUCTS

2731006

*Quala-ty for the
caring professional*

INGREDIENTS: Each gram of Quala 20% benzocaine gel contains between 180-220 mg benzocaine U.S.P., in a water soluble base of PEG 3350 U.S.P., PEG 400 U.S.P., flavor, sodium saccharin U.S.P., and FD&C Red #40.

USUAL DOSAGE: For oral mucosal use only as directed by dentist.

WARNING: Keep out of reach of children. Do not use on people with known allergies to benzocaine and PABA compounds.

Store at controlled room temperature: 59-86°F (15-30°C).

2731006A
(R 8/22/08)

For more information call ADC at 1-800-929-4ADC

Manufactured for  Nashville, TN 37217

MADE IN U.S.A.

Topical Anesthetic Gel

(20% Benzocaine)

Strawberry

For Professional Use Only



2731006

Quala-ty for the
caring professional



+D02327310061-

PRINCIPAL DISPLAY PANEL - 34 g Jar Label - Raspberry

Topical Anesthetic Gel

(20% Benzocaine)

For Professional Use Only

Raspberry

Q®

Quala

DENTAL PRODUCTS

2731007

Quala-ty for the
caring professional

INGREDIENTS: Each gram of Quala 20% benzocaine gel contains between 180-220 mg benzocaine U.S.P., in a water soluble base of PEG 3350 U.S.P., PEG 400 U.S.P., flavor, sodium saccharin U.S.P., FD&C Red #28, FD&C Red #40, and FD&C Blue #1.

USUAL DOSAGE: For oral mucosal use only as directed by dentist.

WARNING: Keep out of reach of children. Do not use on people with known allergies to benzocaine and PABA compounds.

Store at controlled room temperature: 59-86°F (15-30°C).

2731007A
(R 8/22/08)

For more information call ADC at 1-800-929-4ADC

Manufactured for  Nashville, TN 37217

MADE IN U.S.A.

Topical Anesthetic Gel

(20% Benzocaine)

Raspberry

For Professional Use Only



2731007

Quala-ty for the
caring professional



+D02327310071-

TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:43128-021
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	220 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Polyethylene Glycol 3350 (UNII: G2M7P15E5P)	
Polyethylene Glycol 400 (UNII: B697894SGQ)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Water (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43128-021-30	34 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	

TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:43128-023
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	220 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Polyethylene Glycol 3350 (UNII: G2M7P15E5P)	
Polyethylene Glycol 400 (UNII: B697894SGQ)	
Saccharin Sodium (UNII: SB8ZUX40TY)	

Water (UNII: 059QF0K00R)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43128-023-30	34 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	

TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:43128-024
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	220 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Polyethylene Glycol 3350 (UNII: G2M7P15E5P)	
Polyethylene Glycol 400 (UNII: B697894SGQ)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Water (UNII: 059QF0K00R)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	COCONUT (Pina Colada)	Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43128-024-30	34 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	

TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:43128-022
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	220 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Polyethylene Glycol 3350 (UNII: G2M7P15E5P)	
Polyethylene Glycol 400 (UNII: B697894SGQ)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Water (UNII: 059QF0KO0R)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43128-022-30	34 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	

TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:43128-020
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	220 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Polyethylene Glycol 3350 (UNII: G2M7P15E5P)	
Polyethylene Glycol 400 (UNII: B697894SGQ)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Water (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43128-020-30	34 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	

TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:43128-026
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	220 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Polyethylene Glycol 3350 (UNII: G2M7P15E5P)	
Polyethylene Glycol 400 (UNII: B697894SGQ)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Water (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43128-026-30	34 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	

Labeler - NDC, Inc. (009831413)

Establishment

Name	Address	ID/FEI	Business Operations
Caulk		083235549	MANUFACTURE(43128-021, 43128-023, 43128-024, 43128-022, 43128-020, 43128-026)