

**TOPEX- benzocaine gel, dentifrice
DENTSPLY Caulk**

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](#).

**Topex® Topical Anesthetic Gel/Liquid –
20% Benzocaine**

DIRECTIONS FOR USE

Gel – 1oz/30mL

REF AD31001 Cherry

REF AD31002 Mint

REF AD31003 Banana

REF AD31004 Pina Colada

REF AD31005 Bubble-Num

REF AD31006 Strawberry

REF AD31007 Razzberry

Gel – 100g jar

REF AD31064 Cherry

REF AD31964 Mint

REF AD31067 Pina Colada

REF AD31068 Bubble-Num

Liquid – 1oz/30mL

REF AD31011 Cherry

REF AD31012 Mint

REF AD31014 Pina Colada USP – 2oz/57g

NPN Number: 00638358

For dental use only.

USA: Rx only.

1. DESCRIPTION

Flavored 20% benzocaine gel or liquid for topical mucosal anesthesia.

2. INDICATIONS

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 intraoral radiographs.

3. CONTRAINDICATIONS

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

4. WARNINGS

Keep out of reach of children. For professional dental use only.

5. PRECAUTIONS

Topex 20% benzocaine gels and liquids are supplied in multiple use containers. Take care not to contaminate the bottle by reintroducing a used cotton applicator into the bottle.

6. DOSAGE AND ADMINISTRATION

1. Each gram of Topex 20% benzocaine gel or liquid contains between 180-220mg benzocaine in a flavored base.
2. 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.
3. For topical tissue anesthesia during scaling procedures, dispense a small amount of Topex gel or liquid into a dappen dish, then coat the scaler with the product prior to use.
4. Tightly re-cap the jar after each use.

7. STORAGE

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

SultanHealthcare

411 Hackensack Avenue, 9th Floor, Hackensack, NJ 07601

Toll Free: 800-637-8582 • Phone: 201-871-1232

Fax: 201-871-0321 • www.sultanhealthcare.com

Made in the USA

Form #0030502DF (R 7/22/09)

PRINCIPAL DISPLAY PANEL - 100 gram Jar Label

NPN 00638358

TOPEX®
TOPICAL
ANESTHETIC
GEL
(Benzocaine 20%)

CHERRY

Net Content 100g

NPN 00638358

TOPEX®
TOPICAL
ANESTHETIC
GEL
(Benzocaine 20%)
CHERRY
Net Content 100g

DOSE & ADMINISTRATION:
Apply as required to the oral mucosal.

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

Store at controlled room temperature 59-88°F (15-30°C).

Rx Only
For Dental Use Only

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

REF AD31064
Made in U.S.A. Manufactured for:

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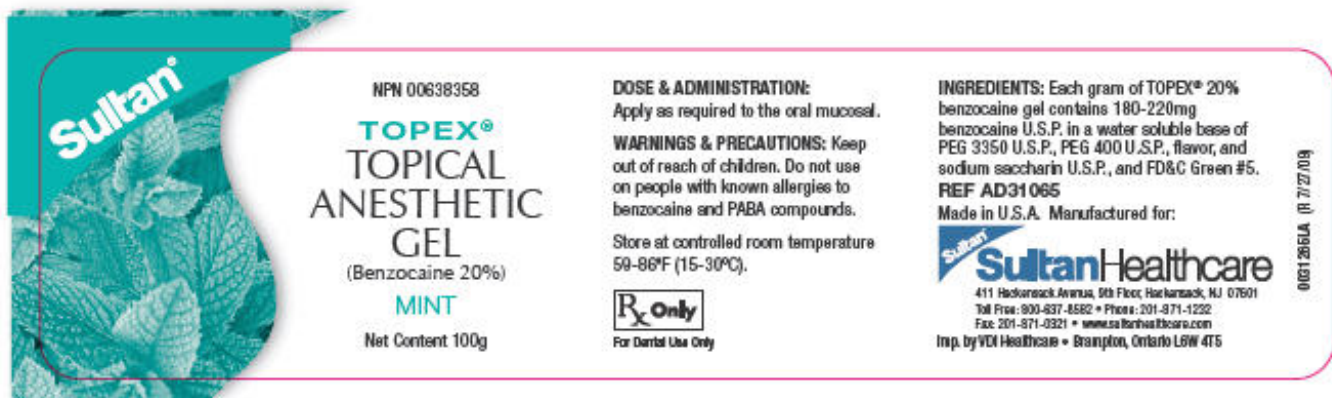
0031284JA (R 7/22/09)

PRINCIPAL DISPLAY PANEL - 100 gram Jar Label

NPN 00638358

TOPEX®

**TOPICAL
ANESTHETIC
GEL**
(Benzocaine 20%)
MINT
Net Content 100g



PRINCIPAL DISPLAY PANEL - 100 gram Jar Label

NPN 00638358

**TOPEX®
TOPICAL
ANESTHETIC
GEL**
(Benzocaine 20%)
PIÑA COLADA
Net Content 100g



PRINCIPAL DISPLAY PANEL - 100 gram Jar Label

NPN 00638358

**TOPEX®
TOPICAL
ANESTHETIC
GEL**
(Benzocaine 20%)

BUBBLE NUM®

Net Content 100g

Sultan

NPN 00638358

TOPEX®
TOPICAL ANESTHETIC GEL
(Benzocaine 20%)
BUBBLE NUM®
Net Content 100g

DOSE & ADMINISTRATION:
Apply as required to the oral mucosal.

WARNINGS & PRECAUTIONS: 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).

Rx Only
For Dental Use Only

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

REF AD31068
Made in U.S.A. Manufactured for:

Sultan Healthcare
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0031288LA (R 7/27/09)

TOPEX

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10216-3071
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

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:10216-3071-1	100 g in 1 JAR		

Marketing Information

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

TOPEX

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10216-3081
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

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:10216-3081-1	100 g in 1 JAR		

Marketing Information

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

TOPEX

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10216-3091
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

Product Characteristics

Color	WHITE	Score	
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Shape		Size	
Flavor	COCONUT (Pina Colada)	Imprint Code	
Contains			
Packaging			
#	Item Code	Package Description	Marketing Start Date
1	NDC:10216-3091-1	100 g in 1 JAR	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	

TOPEX			
benzocaine gel, dentifrice			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10216-3110
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
Product Characteristics			
Color	PINK	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			
Packaging			
#	Item Code	Package Description	Marketing Start Date
1	NDC:10216-3110-1	100 g in 1 JAR	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	

Labeler - DENTSPLY Caulk (083235549)

Establishment

Name	Address	ID/FEI	Business Operations
DENTSPLY Caulk		083235549	MANUFACTURE

Revised: 2/2010

DENTSPLY Caulk