

**SMARTPRACTICE TOPICAL ANESTHETIC GEL PINA COLADA- benzocaine gel**  
**SMARTPRACTICE TOPICAL ANESTHETIC GEL BUBBLE GUM- benzocaine gel**  
**SMARTPRACTICE TOPICAL ANESTHETIC GEL STRAWBERRY- benzocaine gel**  
**SMARTPRACTICE TOPICAL ANESTHETIC GEL CHERRY- benzocaine gel**  
**SMARTPRACTICE TOPICAL ANESTHETIC GEL MINT- benzocaine gel**  
**SMARTPRACTICE TOPICAL ANESTHETIC GEL RASPBERRY- benzocaine gel**  
**SmartHealth, Inc. (DBA SmartPractice)**

*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.*

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**SmartPractice topical anesthetic gel**

**DESCRIPTION**

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

**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 intra- oral radiographs.

**CONTRAINDICATIONS**

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

**WARNINGS**

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

**PRECAUTIONS**

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

**DOSAGE AND ADMINISTRATION**

1. Each gram of benzocaine gel 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 gel into a dappen dish, then coat the scaler with the product prior to use.
4. Tightly re-cap the jar after each use.

**STORAGE**

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

**DISTRIBUTED BY**

distributed by:  
SmartPractice

3400 east mcdowell rd  
phoenix, AZ 85008

Made in USA.

### PRINCIPAL DISPLAY PANEL - Cherry



SP620297 | topical anesthetic gel  
(benzocaine 20%)

800.522.0800  
smartpractice.com

cherry flavor  
Rx only



ingredients: Each gram of 20% benzocaine gel contains between 180-220 mg benzocaine USP in a water soluble base of PEG 3350 USP, PEG 400 USP, flavor, sodium saccharin USP and FD&C Red #40.  
dosage and administration: Apply as required to the oral mucosa.  
warning and precautions: Keep out of the reach of children. Do not use on people with known allergies to benzocaine and PABA compounds.

caution: Federal law (USA) prohibits dispensing without prescription.  
Store between 59-86°F (15-30°C)

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0831001LA Rev. 01

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69521-7021-34

### PRICIPAL DISPLAY PANEL - Mint



SP620298 | topical anesthetic gel  
(benzocaine 20%)

800.522.0800  
smartpractice.com

mint flavor  
Rx only



ingredients: Each gram of 20% benzocaine gel contains between 180-220 mg benzocaine USP in a water soluble base of PEG 3350 USP, PEG 400 USP, flavor, sodium saccharin USP and D&C Green #5.  
dosage and administration: Apply as required to the oral mucosa.  
warning and precautions: Keep out of the reach of children. Do not use on people with known allergies to benzocaine and PABA compounds.

caution: Federal law (USA) prohibits dispensing without prescription.  
Store between 59-86°F (15-30°C)

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69521-7011-34

### PRINCIPAL DISPLAY PANEL - Pina Colada



SP620299 | topical anesthetic gel  
(benzocaine 20%)

800.522.0800  
smartpractice.com

piña colada flavor  
Rx only



ingredients: Each gram of 20% benzocaine gel contains between 180-220 mg benzocaine USP in a water soluble base of PEG 3350 USP, PEG 400 USP, flavor, sodium saccharin USP.

dosage and administration: Apply as required to the oral mucosa.  
warning and precautions: Keep out of the reach of children. Do not use on people with known allergies to benzocaine and PABA compounds.

caution: Federal law (USA) prohibits dispensing without prescription.  
Store between 59-86°F (15-30°C)

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69521-7001-34

### PRINCIPAL DISPLAY PANEL - Bubble Gum



SP620300 | topical anesthetic gel  
(benzocaine 20%)

800.522.0800  
smartpractice.com

bubblegum flavor  
Rx only



ingredients: Each gram of 20% benzocaine gel contains between 180-220 mg benzocaine USP in a water soluble base of PEG 3350 USP, PEG 400 USP, flavor, sodium saccharin USP and D&C Red #28.

dosage and administration: Apply as required to the oral mucosa.  
warning and precautions: Keep out of the reach of children. Do not use on people with known allergies to benzocaine and PABA compounds.

caution: Federal law (USA) prohibits dispensing without prescription.  
Store between 59-86°F (15-30°C)

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69521-7031-34

**PRINCIPAL DISPLAY PANEL - Strawberry**



**SP620301** | **topical anesthetic gel  
(benzocaine 20%)**

800.522.0800  
smartpractice.com

**strawberry flavor**

Rx only



**1 fl. oz. (29.5ml)**

ingredients: Each gram of 20% benzocaine gel contains between 180-220 mg benzocaine USP in a water soluble base of PEG 3350 USP, PEG 400 USP, flavor, sodium saccharin USP and FD&C Red #40.  
dosage and administration: Apply as required to the oral mucosa.  
warning and precautions: Keep out of the reach of children. Do not use on people with known allergies to benzocaine and PABA compounds.

caution: Federal law (USA) prohibits dispensing without prescription.  
Store: between 59-86°F (15-30°C)

distributed by:  
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0831026LA Rev. 01

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69521-7061-34

**PRINCIPAL DISPLAY PANEL - Raspberry**



**SP620311** | **topical anesthetic gel  
(benzocaine 20%)**

800.522.0800  
smartpractice.com

**raspberry flavor**

Rx only



**1 fl. oz. (29.6ml)**

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

dosage and administration: Apply as required to the oral mucosa.  
warning and precautions: Keep out of the reach of children. Do not use on people with known allergies to benzocaine and PABA compounds.

caution: Federal law (USA) prohibits dispensing without prescription.  
Store: between 59-86°F (15-30°C)

distributed by:  
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0831007LA Rev. 02

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69521-7061-34

**SMARTPRACTICE TOPICAL ANESTHETIC GEL PINA COLADA**

benzocaine gel

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:69521-041
<b>Route of Administration</b>	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 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	COCONUT (Pina Colada)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69521-041-34	34 g in 1 BOTTLE, PLASTIC; 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	

**SMARTPRACTICE TOPICAL ANESTHETIC GEL BUBBLE GUM**

benzocaine gel

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:69521-031
<b>Route of Administration</b>	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 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	

**Product Characteristics**

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BUBBLE GUM	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69521-031-34	34 g in 1 BOTTLE, PLASTIC; 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	

## SMARTPRACTICE TOPICAL ANESTHETIC GEL STRAWBERRY

benzocaine gel

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69521-051
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 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	

### 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:69521-051-34	34 g in 1 BOTTLE, PLASTIC; 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	

## SMARTPRACTICE TOPICAL ANESTHETIC GEL CHERRY

benzocaine gel

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69521-021
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 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	

### 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:69521-021-34	34 g in 1 BOTTLE, PLASTIC; 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	

## SMARTPRACTICE TOPICAL ANESTHETIC GEL MINT

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:69521-011
<b>Route of Administration</b>	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
PEPPERMINT OIL (UNII: AV092KU4JH)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0K00R)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69521-011-34	34 g in 1 BOTTLE, PLASTIC; 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	

## SMARTPRACTICE TOPICAL ANESTHETIC GEL RASPBERRY

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:69521-061
<b>Route of Administration</b>	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 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0K00R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

### 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:69521-061-34	34 g in 1 BOTTLE, PLASTIC; 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** - SmartHealth, Inc. (DBA SmartPractice) (061081477)

### Establishment

Name	Address	ID/FEI	Business Operations
Dentsply Caulk		083235549	manufacture(69521-041, 69521-011, 69521-021, 69521-031, 69521-051, 69521-061)

Revised: 12/2017

SmartHealth, Inc. (DBA SmartPractice)