## TOPICAL ANESTHETIC BUBBLE GUM- benzocaine gel Safco Dental Supply Co.

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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#### SensiCaine Topical Anesthetic Gel Bubble Gum Flavor

#### INGREDIENTS

Each gram of 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 D&C Red #28.

#### **USUAL DOSAGE**

For oral mucosal use only as directed by a 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).

#### **CAUTION**

Federal law prohibits dispensing without a prescription.

Distributed by: Safco Dental Supply Co. Buffalo Grove, IL 60089 800-621-2178 www.safcodental.com

#### PRINCIPAL DISPLAY PANEL - Jar Label

SAFCO SensiCaine

Topical Anesthetic Gel

#### **Bubble Gum Flavor**

Contains 20% Benzocaine

For Professional Use Only

1 oz. (34 g)

2131025LA, R1-080312

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Reorder #102-0452

#### TOPICAL ANESTHETIC BUBBLE GUM

benzocaine gel

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:67239-0206 Route of Administration DENTAL

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

Inactive Ingredients		
Ingredient Name	Strength	
Polyethylene Glycol 400 (UNII: B697894SGQ)		
Saccharin Sodium (UNII: SB8ZUX40TY)		
Polyethylene Glycol 3350 (UNII: G2M7P15E5P)		
Water (UNII: 059QF0KO0R)		
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0 Y5NH)		

Product Characteristics		
Color	pink	Score
Shape		Size
Flavor	BUBBLE GUM	Imprint Code
Contains		

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:67239-0206-1	34 g in 1 JAR; Type 0: Not a Combination Product	08/06/2012	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part356	08/06/2012		

## Labeler - Safco Dental Supply Co. (020417380)

### Registrant - Safco Dental Supply Co. (020417380)

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