# TOPICAL ANESTHETIC BUBBLE GUM- benzocaine gel Patters on Dental Supply Inc

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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## Patters on Topical Anesthetic 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 FD&C Red #28.

#### **USUAL DOSAGE**

For oral mucosal use only as directed by a dentist.

#### **CAUTION**

Federal law prohibits dispensing without a prescription.

#### 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).

MADE IN U.S.A.
Distributed by:
PATTERSON DENTAL
Patterson Dental Supply, Inc.
1031 Mendota Heights Road
Saint Paul, MN 55120

#### PRINCIPAL DISPLAY PANEL - 29.6 mL Jar Label

PATTERSON DENTAL

NDC#50227-2114-1

**Topical Anesthetic** 

**Bubble Gum Flavor Gel** 

Contains 20% Benzocaine

For Professional Use Only

Net Contents 1 fl oz (29.6 mL)

Reorder Number 090-0035

0531025LA, R1-021712

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#### TOPICAL ANESTHETIC BUBBLE GUM

benzocaine gel

**Product Information** 

HUMAN OTC DRUG NDC:50227-2114 Product Type Item Code (Source)

**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 Dihydrate (UNII: SB8ZUX40TY)			
Polyethylene Glycol 3350 (UNII: G2M7P15E5P)			
Water (UNII: 059QF0KO0R)			

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:50227-2114-1	29.6 g in 1 JAR		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC MONOGRAPH NOT FINAL	part356	02/19/1963				

# Labeler - Patterson Dental Supply Inc (171843584)

Revised: 4/2012 Patterson Dental Supply Inc