

**TOPICAL ANESTHETIC BANANA- benzocaine gel, dentifrice
Patterson Dental**

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.

**Topical Anesthetic
Banana Flavor Gel**

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 #40.

USUAL DOSAGE

For oral mucosal use only as directed by a dentist.

CAUTION

Contains FD&C Yellow #5 (tartrazine) which may cause an allergic response. 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

Corporate Office

1031 Mendota Heights Road
Saint Paul, MN 55120

PATTERSON
DENTAL /
Montréal Québec
H3M 3E6

PRINCIPAL DISPLAY PANEL - 29.6 mL Label

PATTERSON
DENTAL

Topical Anesthetic

Banana Flavor Gel

Contains 20% Benzocaine

For Professional Use Only
 Net Contents 1 fl oz (29.6 mL)

Reorder Number
089-9989


0531023LA (R 8/22/08)


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TOPICAL ANESTHETIC BANANA
 benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50227-2116
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BANANA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50227-2116-1	34 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 (171843584)

Registrant - DSHealthcare (056296981)

Establishment

Name	Address	ID/FEI	Business Operations
DENTSPLY Caulk		083235549	MANUFACTURE

Revised: 5/2010

Patterson Dental