

TOPICAL ANESTHETIC PINA COLADA- benzocaine gel
Patterson 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.

Patterson Topical Anesthetic Piña Colada 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.

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#50227-2110-1

Topical Anesthetic

Piña Colada Flavor Gel

Contains 20% Benzocaine

For Professional Use Only

Net Contents 1 fl oz (29.6 mL)

Reorder Number

090-0019

0531024LA, R1-021712

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TOPICAL ANESTHETIC PINA COLADA

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 227-2110
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: 059QF0K00R)	

Product Characteristics

Color	YELLOW (Opaque white to yellowish)	Score	
Shape		Size	
Flavor	PINEAPPLE (Pina Colada)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50 227-2110-1	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