TOPICAL ANESTHETIC RASPBERRY- 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 Raspberry 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 #40, FD&C Blue #1 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#50227-2113-1

Topical Anesthetic

Raspberry Flavor Gel

Contains 20% Benzocaine

For Professional Use Only

Net Contents 1 fl oz (29.6 mL)

Reorder Number 090-0043



TOPICAL ANESTHETIC RASPBERRY

benzocaine gel							
Product Information	n						
Product Type		HUMAN OTC DRUG Item Code (Source) N			NDC:5	NDC:50227-2113	
Route of Administration	n	DENTAL					
Active Ingredient/A	ctive Moi	etv					
Ingredient Name Basis of Streng						Strength	
Benzocaine (UNII: U3RSY	-		JW5)	Benzocaine	0	220 mg in 1 g	
Inactive Ingredients	_						
macuve mgreulene	•	Ingredient Nam	<u>م</u>			Strength	
Polyethylene Glycol 400 (UNII: B697894SGQ)						Strength	
Saccharin Sodium Dihydrate (UNII: SB8ZUX40TY)							
Polyethylene Glycol 335							
Water (UNII: 059QF0KO0							
FD&C Red no. 40 (UNII: WZB9127XOA)							
FD&C Blue no. 1 (UNII: H3R47K3TBD)							
Product Characteris	stics						
Color							
Shape		Size					
Flavor	RASPBERF	RASPBERRY Imprint Code					
Contains							
Packaging							
# Item Code	Pack	age Description	Marketing S	Marketing Start Date Mar		rketing End Date	
1 NDC:50227-2113-1	29.6 g in 1	· ·				-	
	-						
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