TOPICAL ANESTHETIC CHERRY- 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.

Patterson Topical Anesthetic Cherry 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.

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#50227-2115-1

Topical Anesthetic

Cherry Flavor Gel

Contains 20% Benzocaine

For Professional Use Only

Net Contents 1 fl oz (29.6 mL)

Reorder Number 089-9997 0531021LA, R1-021712

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TOPICAL ANESTHETIC CHERRY

benzocaine gel

benzocalne gel							
Product Information	n						
Product Type	oduct Type		Item Coc	le (Source)	NDC:	NDC:50227-2115	
Route of Administration	n	DENTAL					
Active Ingredient/A	ctive Moi	ety					
	Ingre	edient Name		Basis of	Strength	Strength	
Benzocaine (UNII: U3RSY	748JW5) (Ben	nzocaine - UNII:U3RS Y48 JW5)		Benzocaine		220 mg in 1 g	
Inactive Ingredients	6						
Ingredient Name						Strength	
Polyethylene Glycol 400 (UNII: B697894SGQ)							
Saccharin Sodium Dihydrate (UNII: SB8ZUX40TY)							
Polyethylene Glycol 3350 (UNII: G2M7P15E5P)							
Water (UNII: 059QF0KO0R)							
Product Characteris	stics						
Color		ED	Score	Score			
Shape			Size	Size			
Flavor CHERRY			Imprint Code				
Contains							
Packaging							
# Item Code	Pack	age Description	Marketing	Start Date	Market	ing End Date	
1 NDC:50227-2115-1	29.6 g in 1	JAR					
Marketing Infor	mation						
Marketing Category	y Appli	ication Number or Mor	ograph Citatio	n Marketing Sta	art Date Ma	rketing End Date	
OTC MONOGRAPH NOT F	INAL part35	6		02/19/1963			

Labeler - Patterson Dental Supply Inc (171843584)

Revised: 4/2012

Patterson Dental Supply Inc