TOPICAL ANESTHETIC MINT- 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.

Patters on Topical Anesthetic Mint 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 Green #5.

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#50227-2112-1

Topical Anesthetic

Mint Flavor Gel

Contains 20% Benzocaine

For Professional Use Only

Net Contents 1 fl oz (29.6 mL)

Reorder Number 090-0001

0531022LA, R1-021712

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TOPICAL ANESTHETIC MINT

benzocaine gel

Product Information

HUMAN OTC DRUG NDC:50227-2112 Product Type Item Code (Source)

Route of Administration DENTAL

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name 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	GREEN	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:50227-2112-1	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