TOPICAL ANESTHETIC BANANA- benzocaine gel, dentifrice Patters on 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 allergenic 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

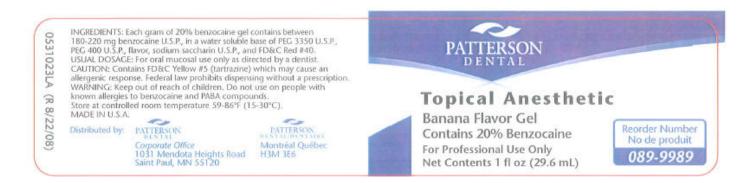
PATTERSON DENTAL

Topical Anesthetic

Banana Flavor Gel Contains 20% Benzocaine

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

Reorder Number **089-9989**



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 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 3350 (UNII: G2M7P15E5P) POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) SACCHARIN SODIUM (UNII: SB8ZUX40TY) FD&C RED NO. 40 (UNII: WZB9127XOA) **Product Characteristics** Color Score Size Shape BANANA Flavor 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			
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Labeler - Patterson Dental (171843584)

Registrant - DSHealthcare (056296981)

Establishment

Name	Address	ID/FEI	Business Operations
DENTSPLY Caulk		083235549	MANUFACTURE

Revised: 5/2010

Patterson Dental