PRECAINE B BUBBLEGUM- benzocaine topical anesthetic gel Pascal Company, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Precaine B Bubblegum

Directions

Application Directions:

For topical use only

For best results apply to previously dried oral mucosa with cotton swab or similar applicator for adquate control of pain

Removal of excess saliva during application minimizes dilution of the anesthetic and permits maximum penetration

Not more than 1.2mg per Kg body weight per patient should be applied during a 24-hour period

Warnings

Warning:

Recommended dosage should not be exceeded due to possible side effects.

Keep out of the reach of children.

For professional use only.

Do not use in the eyes.

Avoid swallowing.

Not for home or unsupervised consumer use.

Not for use on children 2 and younger or pregnant or nursing women.

Contraindications

Precaine B is contraindicated in patients with known hypersensitivity to benzocaine or PABA.

Other Information

For product SDS information, please got to www.pascaldental.com or contact Pascal directly.

Store product between 60 degrees F (16 degrees C) and 86 degrees F (30 degrees C)

Rx only in USA

Made in USA

Precaine B

Precaine B

Topical Anesthetic Gel for oral us

Bubblegum

Contains: Benzocaine 20% in a flavored aqueous bse

Net Contents: 30g

Pascal International

2929 NE Northup Way

Bellevue, WA 98004

425.827.4694

REF 15-350

SN72506/1115

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PRECAINE B BUBBLEGUM

benzocaine topical anesthetic gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10866-0088
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

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Ingredient Name		Basis of Strength	Strength
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE -	UNII:U3RS Y48 JW5)	BENZOCAINE	221 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 934 (UNII: Z135WT9208)	125 mg in 1 g

Product Characteristics			
Color	red	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:10866-0088-1	30 g in 1 JAR; Type 0: Not a Combination Product	0 1/27/20 16	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		0 1/27/20 16	

Labeler - Pascal Company, Inc. (009260217)

Establishment			
Name	Address	ID/FEI	Business Operations
Pascal Company, Inc.		009260217	manufacture(10866-0088)

Revised: 1/2020 Pascal Company, Inc.