PRECAINE B CHOCOLATE VANILLA- 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 Chocolate Vanilla

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 1.2 mg per Kg body weight per patient should be applied during a 24 hour period.

Warnings

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 go to www.pascaldental.com or contact Pascal directly.

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

Rx only in USA

Made in USA

Precaine B Chocolate Vanilla

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- applicator, for adequate control of pain.

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Precaine B

Topical Anesthetic Gel for oral use

Chocolate Vanilla

Contains: Benzocaine 20% in a flavored aqueous base

Net contents: 30g

Pascal International

2929 Northup Way

Bellevue, WA 98004

425-827-4694

REF 15-365

SN72508/0217

PRECAINE B CHOCOLATE VANILLA

benzocaine topical anesthetic gel

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Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10866-0089	
Route of Administration	DENTAL			

Active Ingredient/Active Moiety

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

Prod	nct	Chara	acteri	istics
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2 7 0 4 10 0 1 2 1 2 1 2 2 2 2 2 2 2 2 2 2 2 2					
Color	green	Score			
Shape		Size			

Flavor	VANILLA, CHOCOLATE	Imprint Code					
Contains							
Packaging							
# Item Code	Package Description	Marketing Start Date	Marketing End Date				
1 NDC:10866-0089-1	30 g in 1 JAR; Type 0: Not a Combination Product	08/16/2017					
Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
unapproved drug other		08/16/2017					

Labeler - Pascal Company, Inc. (009260217)

Establishment							
Name	Address	ID/FEI	Business Operations				
Pascal Company, Inc.		009260217	manufacture(10866-0089)				

Revised: 1/2020 Pascal Company, Inc.