

BENZO-JEL - benzocaine gel
Henry Schein, 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.

Benzo-Jel™ Unit Dose

Directions for Use:

- 1. Using the pull tab, peel open the lidding material first exposing the cotton tip applicator and then the individual reservoir of Benzo-Jel.**
- 2. Using the cotton tip applicator, apply Benzo-Jel to the desired mucosa.**

Warnings: Keep out of reach of children. Do not use on people with known allergies to benzocaine.

Storage: Store Benzo-Jel at controlled room temperature, between 59 and 86°F (15 and 30°C).

Caution: Federal law (USA) prohibits dispensing without a prescription.

Ingredients:

Active: Each gram of 20% Benzocaine gel contains 200mg of Benzocaine USP

Inactive:

Strawberry: Polyethylene Glycol 400, Polyethylene Glycol 3350, Sucralose, flavor, FD&C Red # 40

Bubble Gum: Polyethylene Glycol 400, Polyethylene Glycol 3350, Sucralose, flavor, D&C Red # 28

Mint: Polyethylene Glycol 400, Polyethylene Glycol 3350, Sucralose, flavors, D&C Green # 5

For professional use only.

REORDER #'S:

Strawberry (#112-7286)

Bubble Gum (#112-7287)

Mint (#112-7288)

NDC # 0404-0742-01 (Strawberry)

NDC # 0404-0743-01 (Bubble Gum)

NDC # 0404-0741-01 (Mint)

Distributed by (in US only):

HENRY SCHEIN, INC.

135 DURYEA ROAD

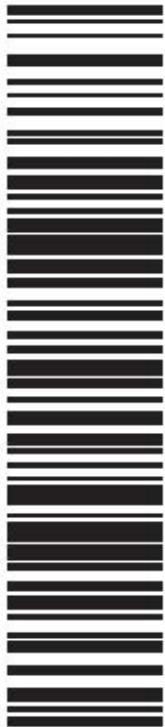
MELVILLE, NY 11747 USA

MADE IN USA

246001 Rev Date: 05/2015

Package Label

+H65811272881L



NDC: 0404-0741-01

 HENRY SCHEIN®

MINT

245931

Unit Dose

Benzo-Jel™

20% Benzocaine
Topical Anesthetic Gel

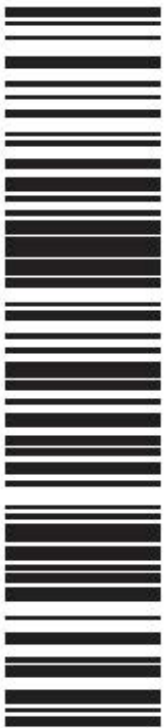
ITEM: 112-7288

LOT: NO VARNISH
AREA

EXP: GREY DOES NOT
PRINT

Rev Date: 04/2015

+H65811272861J



NDC: 0404-0742-01

 HENRY SCHEIN®

STRAWBERRY

245930

Unit Dose

Benzo-Jel™


20% Benzocaine
Topical Anesthetic Gel

ITEM: 112-7286

LOT: NO VARNISH
AREA

EXP: GREY DOES NOT
PRINT

Rev Date: 04/2015



NDC: 0404-0743-01
HENRY SCHEIN
BUBBLE GUM
 245932
Unit Dose
Benzo-Jel™
 20% Benzocaine
 Topical Anesthetic Gel
 ITEM: 112-7287
 LOT: NO VARNISH AREA
 EXP: GREY DOES NOT PRINT
 Rev Date: 04/2015

BENZO-JEL			
benzocaine gel			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0404-0742
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)		Benzocaine	200 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength
Polyethylene Glycol 400 (UNII: B697894SGQ)			
Polyethylene Glycol 3350 (UNII: G2M7P15E5P)			
Sucralose (UNII: 96K6UQ3ZD4)			
Fd&c Red No. 40 (UNII: WZB9127XOA)			
Product Characteristics			
Color	RED	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-0742-01	100 in 1 CARTON	07/03/2015	
1		.56 g in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/03/2015	

BENZO-JEL

benzocaine gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0404-0743
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Polyethylene Glycol 400 (UNII: B697894SGQ)	
Polyethylene Glycol 3350 (UNII: G2M7P15E5P)	
Sucralose (UNII: 96K6UQ3ZD4)	
D&c Red No. 28 (UNII: 767IP0Y5NH)	

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:0404-0743-01	100 in 1 CARTON	07/03/2015	
1		.56 g in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/03/2015	

BENZO-JEL

benzocaine gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0404-0741
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Polyethylene Glycol 400 (UNII: B697894SGQ)	
Polyethylene Glycol 3350 (UNII: G2M7P15E5P)	
Sucralose (UNII: 96K6UQ3ZD4)	
D&c Red No. 28 (UNII: 767IP0Y5NH)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-0741-01	100 in 1 CARTON	07/03/2015	
1		.56 g in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/03/2015	

Labeler - Henry Schein, Inc. (012430880)

Registrant - Henry Schein, Inc. (012430880)

Establishment

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	manufacture(0404-0741, 0404-0742, 0404-0743)

Revised: 10/2018

Henry Schein, Inc.