

GELATO TOPICAL ANESTHETIC- benzocaine gel
Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc.

 IFU available upon request.



GELATO TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68400-503
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	2.4 g in 12 g

Inactive Ingredients

Ingredient Name	Strength
Polyethylene Glycol 400 (UNII: B697894SGQ)	
Polyethylene Glycol 3350 (UNII: G2M7P15E5P)	
Saccharin Sodium (UNII: SB8ZUX40TY)	

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
May contain	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
May contain	FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
May contain	FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
May contain	FD&C RED NO. 40 (UNII: WZB9127XOA)	
May contain	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
May contain	FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

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:68400-503-25	12 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
export only		12/12/2012	

Labeler - Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc. (078654194)

Registrant - Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc. (014769301)

Establishment

Name	Address	ID/FEI	Business Operations
Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc.		078654194	manufacture(68400-503) , label(68400-503)

Revised: 12/2013

Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc.