PCXX ONE MINTE GEL GRAPE EXPLOSION- fluoride treatment gel Ross Healthcare 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.

PCXX ONE MINTE GEL GRAPE EXPLOSION

fluoride treatment gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62007-012
Route of Administration	topical		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM FLUORIDE (UNII: 8 ZYQ 1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	27.2 mg in 1 mg		

Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40 (UNII: WZB9127XOA)	.02 mg in 1 mg		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	.01 mg in 1 mg		

Product Characteristics			
Color	orange	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:62007-012-16	1 mg in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/21/2014	

Labeler - Ross Healthcare Inc. (244249012)

Registrant - Ross Healthcare Inc. (244249012)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ross Healthcare Inc.		244249012	manufacture(62007-012)	

Revised: 5/2014 Ross Healthcare Inc.