PCXX ONE MINTE GEL CREME DE MENTHE- 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 CREME DE MENTHE

fluoride treatment gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62007-006
Route of Administration	topical		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	27.2 mg in 1 mg		

Inactive Ingredients		
Ingredient Name	Strength	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	.03 mg in 1 mg	

Product Characteristics			
Color	green	Score	
Shape		Size	
Flavor	CREME DE MENTHE	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:62007-006-16	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(62007-006)	

Revised: 5/2014 Ross Healthcare Inc.