## PCXX ONE MINTE GEL LUSCIOUS LIME- 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.

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## PCXX ONE MINTE GEL LUSCIOUS LIME

fluoride treatment gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62007-015
Route of Administration	to pic al		

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 RED NO. 40 (UNII: WZB9127XOA)	.01 mg in 1 mg	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	.1 mg in 1 mg	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	0.02 mg in 1 mg	

Product Characteristics			
Color	green	Score	
Shape		Size	
Flavor	LIME	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62007-015-16	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(62007-015)	

Revised: 5/2014 Ross Healthcare Inc.