

PCXX ONE MINTE GEL VANILLA ORANGE- 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 VANILLA ORANGE

fluoride treatment gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62007-011
Route of Administration	topical		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	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)	.02 mg in 1 mg

Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor	VANILLA, ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62007-011-16	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(62007-011)

Revised: 5/2014

Ross Healthcare Inc.