PCXX SNF RNS GRAPE- sodium fluoride rinse 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 SNF RNS GRAPE

Shake well before use. This is a one minute or four minute fluoride gel for in-office patient use. It is normally used as a preventative caries treatment two times a year.

- 1. After thorough prophylaxsis, fill two single or one dual tray, one third full with gel. Air dry teeth and insert trays into the mouth.
- 2. Instruct patient to bite down lightly but firmly for one minute (80% effectiveness) or four minutes (100% effectiveness).
- 3. Remove trays. Instruct patient to expectorate any excess gel and not to eat or drink for at least 30 minute

PCXX SNF RNS GRA sodium fluoride rinse	APE			
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source) NDC:62007-30		NDC:62007-303
Route of Administration	TOPICAL, DENTAL			
Active Ingredient/Active	e Moiety			
Ingredient Name			Basis of	Strength

STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	16.4 mg in 1 mL
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Product Characterist	ics		
Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:62007- 303-64	1900 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/24/2017			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		11/24/2017		

Labeler - Ross Healthcare Inc. (064974821)

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