PCXX ROOTBEER APF F- sodium fluoride aerosol, foam 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 ROOTBEER APF F

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 ROOTBEER APF F

sodium fluoride aerosol, foam

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62007-060
Route of Administration	TOPICAL, DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	0.0272 g in 1 g

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	ROOT BEER	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:62007-060-07	125 g in 1 CAN; Type 0: Not a Combination Product	11/21/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/21/2017	

Labeler - Ross Healthcare Inc. (244249012)

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