

PCXX BUBBLEGUM APF G- sodium fluoride 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 BUBBLEGUM APF GEL

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 prophylaxis, 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 BUBBLEGUM APF G			
sodium fluoride gel			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62007-802
Route of Administration	TOPICAL, DENTAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZY01474W7) (FLUORIDE ION)			

SODIUM FLUORIDE (UNII: 8Z YQ14/4W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	27.2 mg in 1 mL
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Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62007-802-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/04/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/04/2019	

Labeler - Ross Healthcare Inc. (064974821)

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Ross Healthcare Inc.