

PCXX WATERMELON NEUTRAL GL- 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 WATERMELON NEUTRAL 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 WATERMELON NEUTRAL GL			
sodium fluoride gel			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62007-827
Route of Administration	TOPICAL, DENTAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	20 mg in 1 mL

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	WATERMELON	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62007-827-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/22/2019	

Professional use anti-cavity treatment

Directions:

1. Use after prophylaxis.
2. Invert applicator.
3. Place cap to applicator tray and dispense 1/3 of tray with gel.
4. Have patient bite down for up to 4 minutes.
5. Remove trays and use suction to remove excess.
6. Do not eat or drink for 30 minutes after use.

Medicinal ingredients:

2.0% Sodium Fluoride.

Non-medicinal ingredients:

xythol, sucralose, flavor, xanthan gum, water, potassium sorbate, sodium benzoate, red 40.

Does not contain gluten.

Warnings:

Keep out of reach of children.
For adults and children age 6 and older.
Do not swallow. US Rx only.

Remove safety seal inside cap prior to use.

MFG # FL-500-N-WT

NDC# 62007-837-06

Ross Healthcare Inc.

Lynden, WA 98264

1-800-663-8303 or www.rosshc.net



NEUTRAL
2.0% SODIUM FLUORIDE
TOPICAL GEL



475ml / 16 fl oz.

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/22/2019	

Labeler - Ross Healthcare Inc. (064974821)