

**PCXX NAF RNS MINT- sodium fluoird e
Ross Healthcare Inc.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

PCxx NaF RNS Mint

Adults and children 6 years of age and older:

use once a day after brushing your teeth with a toothpaste

remove cap

hold bottle upright and squeeze. Fill to FILL LINE

pour out. Only the correct 10 milliliters dose will pour out

vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out

do not swallow the rinse

do not eat or drink for 30 minutes after rinsing

instruct children under 12 years of age in good rinsing habits (to minimize swallowing)

supervise children as necessary until capable of using without supervision

children under 6 years of age: consult a dentist or doctor.

Keep out of reach of children.

If more than used for rinsing is accidentally swallowed, get medical help or contact Poison Control Center right away.

potassium sorbate, xylitol, sucralose, water

Aids in the prevention of dental cavities

Sodium Fluoride 0.05%

Anticavity

PCXX NAF RNS MINT

sodium fluoirde rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62007-400
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	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.04 mg in 1 mL
XYLITOL (UNII: VCQ006KQ1E)	0.5 mg in 1 mL
SUCRALOSE (UNII: 96K6UQ3ZD4)	0.01 mg in 1 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62007-400-16	1 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/22/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/22/2017	

Labeler - Ross Healthcare Inc. (244249012)

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