

NEUTRAL RINSE - sodium fluoride liquid
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.

ACTIVE INGREDIENTS SECTION

MEDICINAL INGREDIENT: SODIUM FLUORIDE 2.0%

PURPOSE SECTION

FOR TOPICAL USE TO AID IN THE PREVENTION OF DENTAL CARIES.

CHILDREN SECTION

NOT RECOMMENDED FOR USE BY CHILDREN UNDER 6 YEARS OF AGE.

INDICATIONS AND USE SECTION

AID IN THE PREVENTION OF DENTAL CARIES

WARNINGS SECTION

CAUTIONS AND WARNINGS: FOR PROFESSIONAL USE ONLY. DO NOT SWALLOW. US LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

DOSAGE AND ADMINISTRATION SECTION

DIRECTIONS FOR USE:

1. DISPENSE 10ML OF SOLUTION INTO A MEASURING CUP.
2. INSTRUCT PATIENT TO RINSE VIGOROUSLY FOR 1 MINUTE AND THEN EXPECTORATE.
3. FOR MAXIMUM BENEFIT, HAVE PATIENT REPEAT PROCEDURE WITH AN ADDITIONAL 10ML.
4. DO NOT EAT OR DRINK FOR 30 MINUTES AFTER USE.

INACTIVE INGREDIENT SECTION

NON MEDICINAL INGREDIENTS: POTASSIUM SORBATE, PURIFIED WATER, SODIUM SACCHARIN, XYLITOL, MINT FLAVOR, BLUE 1.

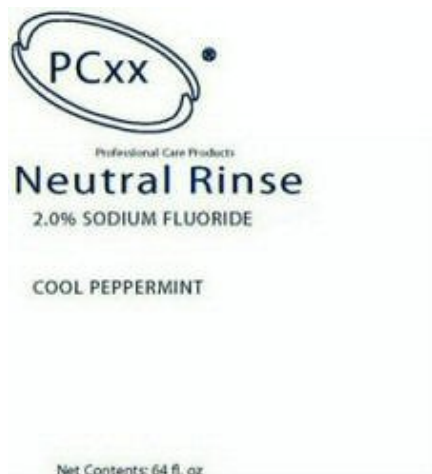
PACKAGE LABEL

PCxx PROFESSIONAL CARE PRODUCTS NEUTRAL RINSE 2.0% SODIUM FLUORIDE COOL PEPPERMINT

NET CONTENTS: 64 FL. OZ

NDC # 62007-210-64

ROSS HEALTHCARE INC. TO FIND AN AUTHORIZED DEALER NEAR YOU VISIT OR CALL



For topical use to aid in the prevention of dental caries.

DIRECTIONS FOR USE:

1. Dispense 10ml of solution into measuring cup.
2. Instruct patient to rinse vigorously for 1 minute and then expectorate.
3. For maximum benefit, have patient repeat procedure with an additional 10ml.
4. Do not eat or drink for 30 minutes after use.

MEDICINAL INGREDIENT: 2.0% Sodium Fluoride

NON MEDICINAL INGREDIENTS: potassium sorbate, purified water, sodium saccharin, xylitol, mint flavor, blue 1.

Cautions and Warnings:

For professional use only. Not recommended for use by children under 6 years of age. Do not swallow. US Law prohibits dispensing without prescription.

NDC# 62007-210-64



TO FIND AN AUTHORIZED DEALER
NEAR YOU VISIT OR CALL:
WWW.ROSSHEALTHCARE.ORG
1-800-663-8303

DELTA, BC
MADE IN CANADA
V3M 6J8

NEUTRAL RINSE

sodium fluoride liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62007-210
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	2 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	blue (BLUE 1)	Score	
Shape		Size	
Flavor	MINT (COOL PEPERMINT)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62007-210-64	1893 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/01/2011	

Labeler - Ross Healthcare, Inc. (244249012)

Registrant - Ross Healthcare, Inc. (244249012)

Establishment

Name	Address	ID/FEI	Business Operations
Ross Healthcare, Inc.		244249012	manufacture

Revised: 10/2011

Ross Healthcare, Inc.