

PCXX ONE MINTE GEL ROOTBEER- fluoride treatment 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.



ONE MINUTE
ACIDULATED PHOSPHATE
FLUORIDE 1.23% TOPICAL GEL



ONE MINUTE
PHOSPHATE ACIDULÉ
GEL FLUOR 1.23% TOPICAL

475ml / 16 fl oz.

Use: Professional Use Anticavity Treatment

Directions:

1. Use after prophylaxis.
2. Insert applicator.
3. Place cap to applicator tray and dispense.
4. Have patient bite down for 1 minute.
5. Remove tray and use suction to remove excess.
6. Do not eat or drink for 30 minutes after use.

Medicinal Ingredients:

1.23% Fluoride Ion

Non-Medicinal Ingredients:

Monosodium phosphate, phosphoric acid, xylitol, sucralose, flavor, xanthan gum, purified water, potassium sorbate.
 Does not contain gluten.

Warnings:

For adults and children age 6 and older.
 Do not swallow
 US Rx

Remove safety seal inside cap prior to use.

LOT 81150659 EX 95 - 2016
 NPN# 02149958 NDC#62007-017-16

Ross Healthcare Inc.
 1-800-863-8300 or www.rosshealthcare.org
 Made in Canada / Fabriqué aux Canada

PCXX ONE MINTE GEL ROOTBEER			
fluoride treatment gel			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62007-028
Route of Administration	topical		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	27.2 mg in 1 mg

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	ROOT BEER	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62007-028-16	1 mg in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/21/2014	

Labeler - Ross Healthcare Inc. (244249012)**Registrant** - Ross Healthcare Inc. (244249012)**Establishment**

Name	Address	ID/FEI	Business Operations
Ross Healthcare Inc.		244249012	manufacture(62007-028)

Revised: 5/2014

Ross Healthcare Inc.