

PCXX ONE MINTE GEL MARSHMALLOW FLOAT- 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, Flavour, 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 B10560729 EX 04 - 2016
NPN# 02199581 NDC#62007-005-16

Ross Healthcare Inc.
1-800-663-8300 or www.rosshealthcare.org
Made in Canada / Fabriqué au Canada

PCXX ONE MINTE GEL MARSHMALLOW FLOAT

fluoride treatment gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62007-005
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	MARSHMALLOW	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62007-005-16	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(62007-005)

Revised: 5/2014

Ross Healthcare Inc.