

**PCXX - sodium fluoride aerosol, foam**  
**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.*

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**Active Ingredient**

ACTIVE INGREDIENT: 2.0% Sodium Fluoride

**Use**

Use: Professional Use Anticavity Treatment

**Keep Out Of Reach Of Children**

Keep out of reach of children.

**Use**

Use: Professional Use Anticavity Treatment

**Cautions and Warnings**

Cautions and Warnings:

Keep out of reach of children. Rx only. Do not puncture or incinerate. Do not store above 50 degrees C. Do not use in the presence of open flame. Contents under pressure. Do not place near any heat source.

**Directions For Use**

DIRECTIONS FOR USE:

1. Use after prophylaxis.
2. Shake bottle vigorously for 3-4 seconds.
3. For adults and children age 6 and older.
4. Invert applicator.
5. Place nozzle to applicator tray and dispense.
6. Allow foam to expand in tray.
7. Have patient bite down for up to 4 minutes.
8. Remove trays and have patient expectorate excess.
9. Do not eat or drink for 30 minutes after use.

## Inactive Ingredients

INACTIVE INGREDIENTS: Glycerin, Xylitol, Sucralose, Poloxamer, Sodium Lauryl Sulphate, Xanthan Gum, Flavour, Potassium Sorbate.

## Product Label

PCxx

Professional Care Products

NEUTRAL FOAM

TOPICAL FLUORIDE FOAM

2.0% Sodium Fluoride

NO FLAVOR

Net Contents: 125 g

NPN# 800004635

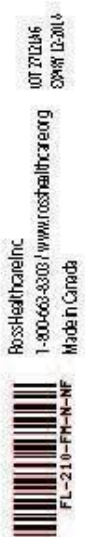
NDC# 062007-105-07

Ross Healthcare Inc. 1-800-663-8303 / [www.rosshealthcare.org](http://www.rosshealthcare.org)

Made in Canada

LOT 27121A6

EXPIRY 12-2014



Professional Care Products  
**NEUTRAL FOAM**  
TOPICAL FLUORIDE FOAM  
2.0% Sodium Fluoride

NO FLAVOR

Net Contents:  
125 g

NPN# 80004635  
NDC# 062007-105-07

Use: Professional Use Amalgam Treatment

DIRECTIONS FOR USE:

1. Use after prophylaxis.
2. Shake bottle vigorously for 2-4 seconds.
3. For adults and children age 8 and older.
4. Invert applicator.
5. Place nozzle to applicator tray and dispense.
6. Allow foam to expand in tray.
7. Have patient bite down for up to 4 minutes.
8. Remove trays and have patient expectorate excess.
9. Do not eat or drink for 30 minutes after use.

ACTIVE INGREDIENT: 2.0% Sodium Fluoride

INACTIVE INGREDIENTS: Glycerin, Xylitol, Sucralose, Poloxamer, Sodium Lauryl Sulfonate, Xanthan Gum, Flavour, Potassium Sorbate.

Caution and Warnings:

Keep out of reach of children. Rx only.  
Do not puncture or incinerate. Do not store above 50°C. Do not use in the presence of an open flame.  
Contents under pressure. Do not place near any heat source.

**PCXX**

sodium fluoride aerosol, foam

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:62007-105
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	2.5 g in 125 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:62007-105-07	125 g in 1 CANISTER		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved drug other		12/12/2012	

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

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Ross Healthcare Inc.		244249012	manufacture(62007-105)