

PCXX VANILLA ORANGE NEUTRAL F- 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.

PCXX VANILLA ORANGE NEUTRAL F

Shake well before use. This is a one minute or four minute fluoride gel for in-office patient use. It is normally used as a preventative caries treatment two times a year.

1. After thorough prophylaxis, fill two single or one dual tray, one third full with gel. Air dry teeth and insert trays into the mouth.
2. Instruct patient to bite down lightly but firmly for one minute (80% effectiveness) or four minutes (100% effectiveness).
3. Remove trays. Instruct patient to expectorate any excess gel and not to eat or drink for at least 30 minute

PCXX VANILLA ORANGE NEUTRAL F			
sodium fluoride aerosol, foam			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62007-101
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	0.02 g in 1 g

Product Characteristics

Color		Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62007-101-07	125 g in 1 CAN; Type 0: Not a Combination Product	11/21/2017	

Use as Professional Use Oral Care Only. This is an anti-

Directions:

1. Use after prophylaxis.
2. Insert applicator.
3. Place applicator applicator over interdental space.
4. Press gently down for 10-15 seconds.
5. Remove applicator and use suction to remove excess.
6. Do not eat or drink for 30 minutes after use.

Medicinal Ingredients:

2.0% Sodium Fluoride
Non-Medicinal Ingredients:
glycerine, xylitol, saccharin, carboxymethylcellulose, sodium lauryl sulfate, water, flavour, parabens, sorbitol.

Does not contain gluten.

Warnings:

For adults and children aged 6 and older.
Do not swallow. Use only as directed.
Do not use before use. Do not puncture or incise. Do not use over 50°C.
Do not use in presence of open flame or spark. Contents under pressure. Do not place in hot or near or over sources of heat.

EX 191034 LOT 103013

NPI# 66007020
Roche Laboratories Inc.
1-800-833-6000 or 1-416-291-1000
Made in Canada / Fabriqué au Canada



NEUTRAL FOAM
2.0% SODIUM FLUORIDE
TOPICAL GEL



2.0% FLUORIDE OF SODIUM
MOUSSE TOPIQUE

1.23g

Mode d'emploi: Utiliser après prophylaxie pour l'application professionnelle.

Mode d'emploi:

1. Utiliser après prophylaxie.
2. Insérer l'applicateur.
3. Placer le bout horizontal de l'applicateur sur l'espacement interdental.
4. Appuyer doucement pendant 10-15 secondes.
5. Retirer l'applicateur et utiliser l'aspiration pour éliminer l'excès.
6. Ne pas manger ou boire pendant 30 minutes après utilisation.

Ingédients médicamenteux:

2,0% Fluorure de Sodium
Ingédients non médicamenteux:
glycérol, polyéthylène, laurylsulfate de sodium, xylitol, saccharine, eau, sorbitol, parabènes, sorbitol.

Ne contient pas de gluten.

Avertissements:

Pour les adultes et les enfants de 6 ans et plus. Ne pas avaler.
Après utilisation, évitez de manger ou de boire pendant 30 minutes. Ne pas utiliser en présence de flamme ou de source de chaleur.
Contenu sous pression. Ne pas placer dans une source de chaleur.

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/21/2017	

Labeler - Ross Healthcare Inc. (064974821)

Revised: 1/2024

Ross Healthcare Inc.