

PCXX ONE MINTE BAZOOKA BUBBLEGUM- 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.

Professional use anti-caries treatment

Directions:

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

Medical Ingredient:
1.23% Fluoride Ion

Non-Medical Ingredients:
Monosodium phosphate, phosphoric acid, xylitol, sucralose, flavor, xanthan gum, water, potassium sorbate, red 40.

Does not contain gluten.

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

Remove safety seal inside cap prior to use.

ME 193036 LOT 062033
yvwkl
NPN# 02146958 NDC62007-002-16



**ONE MINUTE
ACIDULATED PHOSPHATE
FLUORIDE 1.23% ION
TOPICAL GEL**



**PHOSPHATE ACIDULÉ
GEL TOPIQUE AU FLUORURE
1.23% ION FLUORURE**

475ml / 16 fl oz.

Préparation anti-caries

Utilisation:

1. Utiliser après le traitement prophylaxique.
2. Retourner l'applicateur.
3. Distribuer le produit dans les gouttières.
4. Demander au patient de mordre pendant de 1 minute, jusqu'à un maximum de 6 minutes.
5. Retirer les gouttières et utiliser la suction pour retirer l'excédent.
6. Éviter de manger ou de boire pendant 30 minutes après l'application.

Ingédient Médicinal :
1.23% Ion fluorure

Ingédient non Médicinal :
Phosphate de monosodium, acide de phosphorique, xylitol, sucralose, saveur, gomme de xanthane, eau, sorbate de potassium, rouge 40.

Ne pas contenir gluten.

Advertisement :
Garder hors de la portée des enfants.
Destiné aux adultes et aux enfants de 6 ans et plus. Ne pas avaler.

Retirer le sceau de sécurité sous le bouchon avant l'utilisation.

Ross Healthcare Inc.
1-800-663-8303 or www.rhshc.org
Made in Canada / Fabriqué au Canada

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Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:62007-002

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	pink	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62007-002-16	1 mg in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	11/07/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/07/2017	

Labeler - Ross Healthcare Inc. (244249012)

Registrant - Ross Healthcare Inc. (244249012)

Establishment

Name	Address	ID/FEI	Business Operations
Ross Healthcare Inc.		244249012	manufacture(62007-002)

Revised: 11/2017

Ross Healthcare Inc.