PERFECT CHOICE- sodium fluoride and hydrofluoric acid gel Young Dental Manufacturing Co 1, LLC.

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.

Indications and Usage:

Topical application of APF gel is indicated in the prevention of dental caries.

Warning:

Keep out of reach of children. Do not swallow.

If swallowed during treatment, administer milk, limewater, or antacid. If larger dose is ingested (more than 1/4 ounce), contact poison control and immediately seek medical help.

Precautions:

For professional use only. Repeated use may cause dulling of porcelain and ceramic restorations.

Adverse reactions:

Developing teeth of children under age 6 may become permanently discolored if excessive amounts are repeatedly swallowed. Individuals hypersensitive to fluoride may have an adverse reaction.

Dosage and Administration:

After thorough prophylaxis, place gel in applicator tray (not more than 1/3 full). Throughly air-dry teeth and insert tray(s) in mouth. Gel may also be swab applied. Instruct patient to bite down slightly but firmly for one to four minutes. A slight chewing motion enhances coverage interproximally. Remove tray(s) and have patient expectorate excess gel. Instruct patient not to eat, drink or rinse for at least 30 minutes.

How Supplied:

A gel, one bottle contains up to 68 individual applications. Store at controlled room temperature 20°-25°C (68°-77°F).

Do not allow to freeze.

Active Ingredients:

1.23% w/w Fluoride Ion (0.79% from Sodium Fluoride and 0.44% from Hydrogen Fluoride) in 0.1 Molar Phosphoric Acid

Contains: FD&C Red #40

Reorder NO. APF 205PS

TIME TO REORDER! CALL YOUR DENTAL DEALER.

DISTRIBUTED BY

BIOTROL

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Questions or Comments?

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Principal Display Panel

NDC 0273-7006-16

perfectchoice®

One

 $Minute^{\,TM}$

APF Topical Gel

60 Second Treatment

Acidulated Phosphate Fluoride

1.23% Fluroide Ion

Rx only

Peppermint Stick

Net Weight: 17.5 oz. (497g)



PERFECT CHOICE

sodium fluoride and hydrofluoric acid gel

Product Information						
Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:0273- 7006			
Route of Administration	DENTAL	DEA Schedule				

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
Sodium Fluoride (Fluoride Ion)	Fluoride Ion	7.9 mg in 1 g			
HYDROFLUORIC ACID (FLUORIDE ION)	FLUORIDE ION	4.4 mg in 1 g			

Product Characte	ristics	
Color		Score
Shape		Size

Flavor	PEPPERMINT (Peppermint Stick)		Imprint	Imprint Code			
Contains							
Packaging							
# Item Code	Package Description	Marketing Start Date		Mar	Marketing End Date		
1 NDC:0273-7006-16	497 g in 1 BOTTLE						
Marketing Information							
Marketing Categor	y Application Number or Monogra	aph Citation	Marketing Start Date		Marketing End	Date	
unapproved drug other			08/31/2006				

Labeler - Young Dental Manufacturing Co 1, LLC. (006309355)

Revised: 11/2012 Young Dental Manufacturing Co 1, LLC.