

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.

APF Gel - Watermelon

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. Do not use on patients with an allergy to fluoride.

Precautions:

For professional use only. This product is not intended for home or unsupervised consumer use. 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). Thoroughly 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 thixotropic 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:

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.

Principal Display Panel

NDC 0273-7002-16

ZOOBY

PERFECT CHOICE®

1.23% APF TOPICAL GEL

TURTLE

MELON

60-Second

Treatment Acidulated

Phosphate Fluoride

1.23% Fluoride Ion

Net Weight: 17.5 oz. (497g)



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(800)227-3321

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12000345C - 05/15

PERFECT CHOICE

sodium fluoride and hydrofluoric acid gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0273-7002
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROFLUORIC ACID (UNII: RGL5YE86CZ) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	4.4 mg in 1 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	7.9 mg in 1 g

Product Characteristics

Color		Score	
Shape		Size	
Flavor	WATERMELON (Turtle Melon)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0273-7002-16	497 g in 1 BOTTLE; Type 0: Not a Combination Product	12/22/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/22/2018	

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

Revised: 12/2018

Young Dental Manufacturing Co 1, LLC.