## 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.

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#### **APF Gel - Bubble Gum**

#### **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). 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 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:**

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 0273-7005-16

**ZOOBY®** 

PERFECT CHOICE®

1.23% APF TOPICAL GEL

**GATOR** 

 $GUM^{TM}$ 

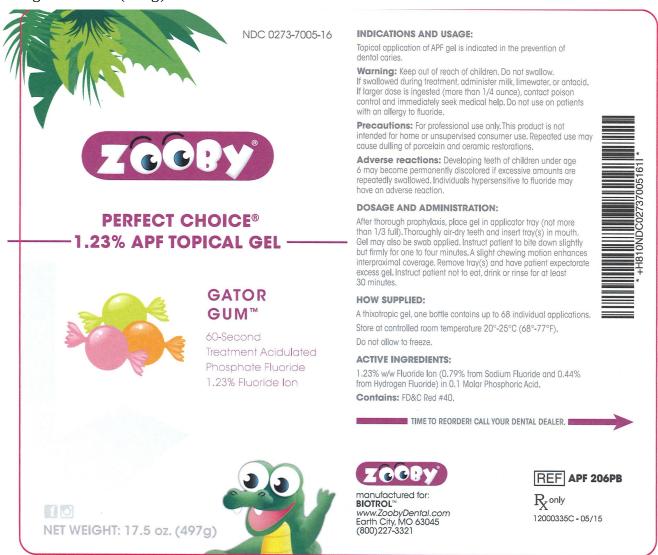
60-Second

Treatment Acidulated

Phosphate Fluoride

1.23% Fluroide Ion

Net Weight: 17.5 oz. (497g)



## PERFECT CHOICE

sodium fluoride and hydrofluoric acid gel

### **Product Information**

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0273-7005
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	7.9 mg in 1 g
HYDROFLUORIC ACID (UNII: RGL5YE86CZ) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	4.4 mg in 1 g

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BUBBLE GUM (Gator Gum)	Imprint Code	
Contains			

ı	Packaging				
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1	NDC:0273-7005-16	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.