

**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 - Marshmallow**

**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 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:**

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

**Principal Display Panel**

NDC 0273-7007-16

ZOUBY®

PERFECT CHOICE®

1.23% APF TOPICAL GEL

HAPPY

HIPPO CAKE®

60-Second

Treatment Acidulated

Phosphate Fluoride

1.23% Fluoride Ion

Net Weight: 17.5 oz. (497g)



NDC 0273-7007-16



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\*+H810NDC02737007161K\*

TIME TO REORDER! CALL YOUR DENTAL DEALER. →



NET WEIGHT: 17.5 oz. (497g)



manufactured for:  
**BIOTROL™**  
www.ZoobyDental.com  
Earth City, MO 63045  
(800)227-3321

**REF APF 203MM**

R<sub>x</sub> only

12000215C - 05/15

**PERFECT CHOICE**

sodium fluoride and hydrofluoric acid gel

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0273-7007
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	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	MARSHMALLOW (Happy Hippo Cake)	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0273-7007-16	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** - Medical Products Laboratories, Inc (002290302)**Establishment**

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc		002290302	manufacture(0273-7007)

Revised: 12/2018

Young Dental Manufacturing Co 1, LLC.