

ALPHA-PRO- sodium fluoride and hydrofluoric acid gel
Dental Technologies, 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.

DTI APF - Vanilla Orange

Indications and Usage:

Topical application of APF gel is indicated in the prevention of dental caries. This treatment is normally used two times per year and should not exceed four times per year.

Contraindications:

Hypersensitivity to fluoride.

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. Contains FD&C Yellow No.6.

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. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.

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 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.

DENTAL TECHNOLOGIES

LINCOLNWOOD, ILLINOIS 60712 USA

www.dentaltech.com

Questions or Comments?

Call: 1-800-835-0885 (US) or 1-847-677-5500

PM-5098 Rev002

Principal Display Panel

DENTAL TECHNOLOGIES

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ALPHA-PRO® APF

TOPICAL GEL

60 SECOND TREATMENT

Acidulated Phosphate Fluoride

1.23% Fluoride Ion

Rx Only

Vanilla Orange

REF No. 009-4301-002

NET WEIGHT: 17.5 oz. (497g)

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www.dentaltech.com

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1.23% Fluoride Ion

Rx Only



Vanilla Orange

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PM-5098 Rev002

sodium fluoride and hydrofluoric acid gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:55346-0943
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	7.9 mg in 1 g
HYDROFLUORIC ACID (UNII: RGL5YE86CZ) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	4.4 mg in 1 g

Product Characteristics

Color		Score	
Shape		Size	
Flavor	ORANGE (Vanilla Orange)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55346-0943-1	497 g in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/01/2013	

Labeler - Dental Technologies, Inc. (148312838)

Revised: 11/2025

Dental Technologies, Inc.