

**PRIMO APF- sodium fluoride gel**  
**Tri State Dental**

*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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**Active Ingredient:**

Fluoride Ion 1.23%

Available from 2.09% Sodium Fluoride and Hydrofluoric Acid

**Purpose:**

Fluoride Treatment Gel

**Indications and Usage:**

- A stable thixotropic fluoride treatment gel used to help prevent dental decay.
- For Professional Use Only. This product is not intended for home or unsupervised use.

**Warnings:**

- Keep out of reach of children.
- Do not swallow. If product is accidentally swallowed in quantities greater than would normally occur with a treatment gel, seek medical help or contact a Poison Control Center right away.
- Read directions carefully before using.

**Dosage and Administration:**

Shake well before use. This is a one minute or four minute fluoride gel for in-office patient use. It is normally used as a preventative caries treatment two times a year.

1. After thorough prophylaxis, fill two single or one dual tray, one third full with gel. Air dry teeth and insert trays into the mouth.
2. Instruct patient to bite down lightly but firmly for one minute (80% effectiveness) or four minutes (100% effectiveness).
3. Remove trays. Instruct patient to expectorate any excess gel and not to eat or drink for at least 30 minutes.

**Other Information:**

Store at controlled room temperature 59° to 86°F (15°-30°C).

Protect from freezing.

### Inactive Ingredients:

Citric Acid, FD&C Blue #1, FD&C Red #40, FD&C Yellow #5 (tartrazine) as a color additive, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xanthan Gum, Xylitol.

# Primo APF GEL

Acidulated Phosphate  
Fluoride Treatment Gel  
*with Xylitol*

1.23% Fluoride Ion

PIÑA COLADA  
Re-order #: FGPC

GLUTEN FREE

RxOnly

Net wt. 16 oz (454 g)

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Fluoride Ion 1.23% ..... Fluoride Treatment Gel  
Available from 2.09% Sodium Fluoride and Hydrofluoric  
Acid.

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Manufactured for:



845 Third Avenue  
6th Floor  
New York, NY 10022  
800-232-6874

[www.primodentalproducts.com](http://www.primodentalproducts.com)

MADE IN THE USA

99092484 Rev 9/13

## PRIMO APF

sodium fluoride gel

### Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:69509-054

<b>Route of Administration</b>	DENTAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	5.6 g in 454 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	PINEAPPLE (PINA COLADA)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69509-054-15	454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/01/2013	

**Labeler** - Tri State Dental (176048478)

