

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](#).

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, 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

COTTON CANDY

Re-order #: FGCC

GLUTEN FREE

 RxOnly

Net wt. 16 oz (454 g)

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Acid.

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Manufactured for:



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

www.primodentalproducts.com

MADE IN THE USA

99092492 Rev 9/13

PRIMO APF

sodium fluoride gel

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:69509-056

Route of Administration		DENTAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	5.6 g in 454 g	
Inactive Ingredients				
Ingredient Name			Strength	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)				
PHOSPHORIC ACID (UNII: E4GA8884NN)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
WATER (UNII: 059QF0KO0R)				
XANTHAN GUM (UNII: TTV12P4NEE)				
XYLITOL (UNII: VCQ006KQ1E)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	blue	Score		
Shape		Size		
Flavor	COTTON CANDY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69509-056-15	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)