

**MS APF- sodium fluoride gel**  
**M&S Dental Supply Co., 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.*

-----

**Active Ingredient:**

Fluoride Ion 1.23%.....Flouride Treatment Gel

Available from 2.09% Sodium Fluoride and Hydrofluoric Acid

**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, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xanthan Gum, Xylitol. May contain blue #1, green #3, red #3, red #40, yellow #5(tartrazine), yellow #6 as a color additive.



**Active ingredient:**  
Fluoride Ion 1.23% ..... Fluoride Treatment Gel Available from 2.09% Sodium Fluoride and Hydrofluoric Acid.

**Purpose:**

**Indications and usage:**

- A stable thixotropic fluoride treatment gel used to help prevent dental decay.
- For Professional Office Use Only. This product is not intended for home or unsupervised consumer 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 twice 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, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xanthan Gum, Xylitol. May contain blue #1, green #3, red #3, red #40, yellow #5 (tartrazine), yellow #6 as a color additive.

# APF GEL THIXOTROPIC

WITH XYLITOL

ACIDULATED PHOSPHATE FLUORIDE TREATMENT GEL  
1.23% FLUORIDE ION

GLUTEN FREE

RX ONLY

Flavor label applied here

**1 MINUTE TO 4 MINUTE TREATMENT**

FOR PROFESSIONAL USE ONLY

**IMPORTANT: READ DIRECTIONS FOR PROPER USE**

Manufactured for:



105-30 101 Avenue  
Ozone Park, NY 11416  
(888) 226-7975

9902850 Rev 10'14

**NET WT. 16 OZ. (454G)**



**BUBBLE GUM**  
Re-order# MS-FGBG



**CHERRY**  
Re-order# MS-FGCH



**COTTON CANDY**  
Re-order# MS-FGCC



**GRAPE**  
Re-order# MS-FGG



**MANGO SMOOTHIE**  
Re-order# MS-FGMS



**MARSHMALLOW**  
Re-order# MS-FGMM



**MINT**  
Re-order# MS-FGM



**ORANGE VANILLA**  
Re-order# MS-FGOV



**PINA COLADA**  
Re-order# MS-FGPC



**STRAWBERRY**  
Re-order# MS-FGSTR

**MS APF**  
sodium fluoride gel

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:69745-012
<b>Route of Administration</b>	DENTAL		

### 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>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BUBBLE GUM	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69745-012-15	454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2014	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/01/2014	

**Labeler** - M&S Dental Supply Co., LLC (173747767)