## 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.

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## **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 prophylaxsis, 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

I MINUTE TO 4 MINUTE TREATMENT

FOR PROFESSIONAL USE ONLY

IMPORTANT: READ
DIRECTIONS FOR PROPER USE

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Purpose:

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Manufactured for:

DENTAL SUPPLY CO LLC. 105-30 101 Avenue

SUPPLY CO LLC. 105-30 101 Avenue Ozone Park, NY 11416 (888) 226-7975

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





















## **MS APF**

sodium fluoride gel

## **Product Information**

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69745-014
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	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)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
WATER (UNII: 059QF0KO0R)		
XANTHAN GUM (UNII: TTV12P4NEE)		
XYLITOL (UNII: VCQ006KQ1E)		

Product Characteristics			
Color	yellow	Score	
Shape		Size	
Flavor	PINEAPPLE (Pina Colada)	Imprint Code	
Contains			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:69745- 014-15	454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2014	

Category Citation Date D	rketing Information			
unapproved drug	eting End Date			
unapproved drug other 10/01/2014				

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

Revised: 1/2022 M&S Dental Supply Co., LLC