

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.



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

Purpose:

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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-FGDH



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



PIÑA COLADA
Re-order# MS-FGPC



STRAWBERRY
Re-order# MS-FGSTR

MS APF
sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69745-013
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)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69745-013-15	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)