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 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.

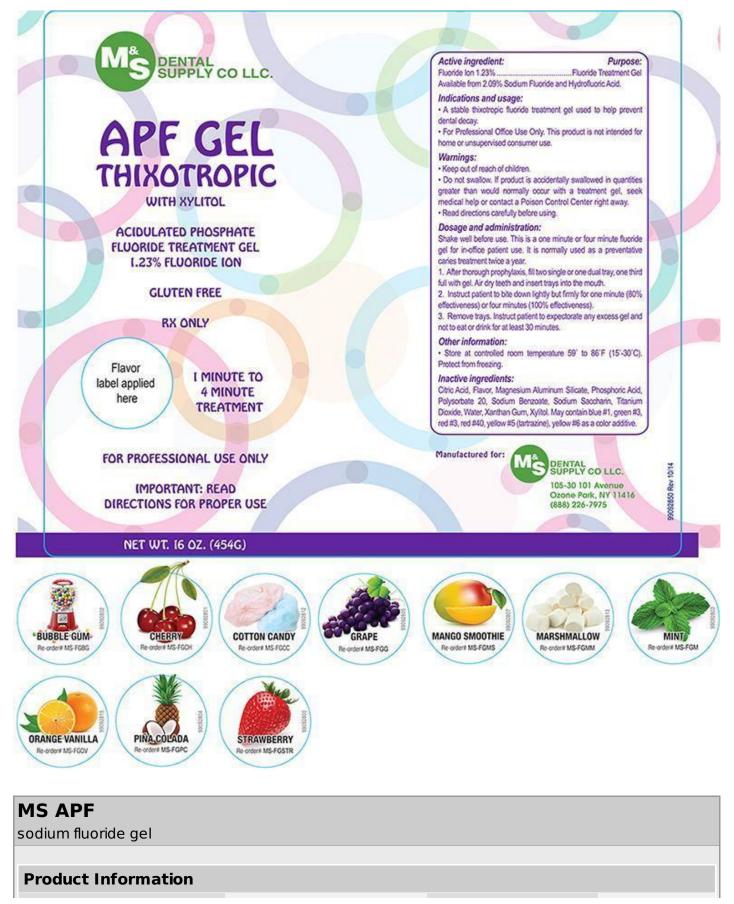
Other Information:

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.



Product Type	•	HUMAN PRESCRIPTION DRUG		Item Code (Source)		NDC:69745-015	
Route of Adm	Administration DENTAL						
Active Ingr	edient/Active	Moiety					
Ingredient Name Basis of Str					Basis of Stre	ngth	Strength
SODIUM FLUO	RIDE (UNII: 8ZYQ14	174W7) (FLUORIDE ION -	UNII:Q80VPU	J408O)	FLUORIDE ION		5.6 g in 454 g
Inactive Ing	gredients						
Ingredient Name							Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)							
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)							
PHOSPHORIC ACID (UNII: E4GA8884NN)							
POLYSORBATE	20 (UNII: 7T1F30V	5YH)					
SODIUM BENZOATE (UNII: OJ245FE5EU)							
SACCHARIN SC	DIUM (UNII: SB8Z	UX40TY)					
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)							
WATER (UNII: 059QF0KO0R)							
XANTHAN GUM (UNII: TTV12P4NEE)							
Product Ch	aracteristics						
Color		purple Score					
Shape		le su le se	Size				
Flavor		GRAPE	Imprint Code				
Contains							
contains							
Packaging							
# Item Cod	e Pa	ackage Description		Ма	rketing Start Date	Mar	keting End Date
	454 g in 1 POT	in 1 BOTTLE, PLASTIC; Type 0: Not a ination Product			/2014		
1 NDC:69745- 015-15	Combination Pr						
• 015-15		oduct					
• 015-15	Combination Pr g Informat g Applica	oduct	nograph		keting Start Date	Mar	keting End Date

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