

IONITE APF- sodium fluoride gel
Dharma Research, inc.

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](#).

- Store at 59° - 86°F (15° - 30°C)
- Protect from freezing
- Ionite APF Gel is free of gluten, soymilk, egg peanut and free of nut products

Citric Acid, Flavor, Hydrofluoric Acid, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Purified Water, Sodium Benzoate, Sodium Saccharin, Sweetness Enhancer, Titanium Dioxide, Tocopheryl Acetate, Xanthan Gum, Xylitol.

- Keep out of the 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.
- Do not use on patients with an allergy Fluoride.
- Ionite APF Gel contains artificial color, confirm that no known patient allergies exist.
- For professional use only.

- Shake well before use.
- This is a four minute or one minute Fluoride gel for in-office patient use.
- For best results, use at least twice a year.
- After thorough prophylaxis, fill two single or one dual tray one third full with gel. Air dry teeth and insert trays into the mouth.
- Instruct patient to bite down lightly but firmly for one minute (80% effectiveness) or four minutes (100% effectiveness)
- Remove trays, instruct patient to expectorate any excess gel and not to eat or drink for at least 30 minutes

NDC# 53045-207-17



DYE FREE

APF THIXOTROPIC GEL
with Xylitol & Vitamin E

Acidulated
Phosphate Fluoride
Treatment Gel
1.23% Fluoride Ion

GLUTEN FREE

1 minute or 4 minute
Treatment

 Only

17 fl. oz. (500ml)

MADE IN USA

Drug Facts

Active Ingredient Sodium Fluoride 2.09%	Purpose Anticaries
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Uses Prescription fluoride treatment gel used to prevent dental decay.

Warnings

- Keep out of the 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.
- Do not use on patients with an allergy to fluoride.
- Ionite APF Gel contains artificial color, confirm that no known patient allergies exist.
- For professional use only.

Directions

- Shake well before use.
- This is a four minute or one minute fluoride gel for in-office patient use.
- For best results, use at least twice a year.
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Other information

- Store at 59° – 86°F (15°-30° C).
- Protect from freezing.
- Ionite APF Gel is free of gluten, soy milk, egg, peanut and tree nut products.

Inactive ingredients
Citric Acid, Flavor, Hydrofluoric Acid, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Purified Water, Sodium Benzoate, Sodium Saccharin, Sweetness Enhancer, Titanium Dioxide, Tocopheryl Acetate, Xanthan Gum, Xylitol.

Manufactured by
DHARMA
RESEARCH, INC.
WWW.DHARMARESEARCH.COM
5220 N.W. 72 Avenue
Unit 1a, Miami, FL 33166
1-877-833-3725

Re-order#: **56-00040**



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IONITE APF

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53045-207
Route of Administration	DENTAL, TOPICAL, ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	6.027 g in 490 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	VANILLA (French Vanilla)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-207-17	490 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2013	

Labeler - Dharma Research, inc. (078444642)

Registrant - Dharma Research, inc. (078444642)

Establishment

Name	Address	ID/FEI	Business Operations
Dharma Research, inc.		078444642	manufacture(53045-207)