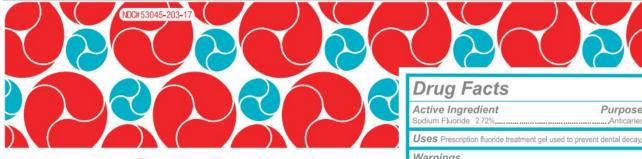
IONITE APF- sodium fluoride gel Dharma Research, inc.

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, FD & C Red No. 40 (C.I. 16035), Flavor, 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 kno.wn 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



Marshmallow Onto

APF THIXOTROPIC GEL with Xylitol & Vitamin E

Acidulated Phosphate Fluoride Treatment Gel 1.23% Fluoride Ion

GLUTEN FREE

1 minute or 4 minute Treatment



17 fl. oz. (500ml)

Purpose

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.
- 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.

Other information

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

Inactive ingredients

Citric Acid, FD&C Red No. 40 (C.I. 16035), Flavor, Magnesium Aluminum Silicate. Phosphoric Acid, Polysorbate 20, Purified Water, Sodium Beczoate, Sodium Sacharin, Sweetness Enhancer, Titanium Dioxide, Tocopheryl Acetate, Xantham Gum, Xyilol.





MADE IN USA

IONITE APF

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53045-203

DENTAL, ORAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	6.027 g in 490 g

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
MAGNESIUM ALUMINUM SILICATE (UNII: 6 M3P6 4 V0 NC)		

PHO SPHO RIC ACID (UNII: E4GA8884NN)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
.ALPHATO CO PHERO L ACETATE, DL- (UNII: WR1WPI7EW8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MARSHMALLOW	Imprint Code	
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-203-17	490 g in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/20 13	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		0 1/0 1/20 13	

Labeler - Dharma Research, inc. (078444642)

Registrant - Dharma Research, inc. (078444642)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dharma Research, inc.		078444642	manufacture(53045-203)	

Revised: 11/2020 Dharma Research, inc.