

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 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#53045-203-17

Marshmallow **ionite****APF THIXOTROPIC GEL**
with Xylitol & Vitamin EAcidulated
Phosphate Fluoride
Treatment Gel
1.23% Fluoride Ion**GLUTEN FREE**1 minute or 4 minute
Treatment

17 fl. oz. (500ml)

Drug Facts**Active Ingredient**
Sodium Fluoride 2.72% **Purpose**
Anticaries**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.
- 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.
- Ionite 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 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 15, Miami, FL 33166
1-877-833-3725

Rev. B, Date: 05/14/2020

Re-order#: **56-00004****MADE IN USA****IONITE APF**

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53045-203
Route of Administration	DENTAL, 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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	

PHOSPHORIC ACID (UNII: E4GA8884NN)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)				
XANTHAN GUM (UNII: TTV12P4NEE)				
XYLITOL (UNII: VCQ006KQ1E)				
Product Characteristics				
Color	Score			
Shape	Size			
Flavor	MARSHMALLOW	Imprint Code		
Contains				
Packaging				
#	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	01/01/2013	
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(53045-203)