

**IONITE APF FOAM- sodium fluoride aerosol, foam**  
**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](#).*

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Castor Oil, Decyl Glucoside, Distilled Water, Flavor, Hydrofluoric Acid, Phosphoric Acid, Poloxamer, Propellant A31, Sodium Benzoate, Sodium Laureth Sulfate, Sodium Saccharine, Triethanolamine, Xylitol

- Do not swallow.
  - Keep out of reach of children.
  - Contents under pressure.
  - Do not place in hot water or near radiators, stoves or other sources of heat.
  - Do not puncture or incinerate container. Do not spray towards open flames.
  - For professional use only.
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- Remove cap from can. Prior to each use, shake can thoroughly for at least 15 seconds.
  - To dispense, invert the can completely upside down. Slowly depress nozzle to dispense foam into a fluoride tray (foam will expand slightly higher than fluoride tray).
  - Air dry teeth thoroughly and inset tray(s) into patient's mouth. Instruct patient to bite down and leave the tray in contact with the teeth between 1 - 4 minutes.
  - Use a saliva ejector during treatment to minimize ingestion of product.
  - Remove the tray(s) and have patient expectorate.
  - Instruct patient not to eat, drink or rinse for 30 minutes after treatment.

NDC# 53045-252-44

### Drug Facts

Active Ingredient	Purpose
1.23% Fluoride Ion	Fluoride Treatment Foam

**Uses** This is a prescription fluoride treatment foam used to help prevent dental decay.

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  - Keep out of the reach of children.
  - Contents under pressure.
  - Do not place in hot water or near radiators, stoves or other sources of heat.
  - Do not puncture or incinerate container. Do not spray toward open flame.
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- Directions**
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**Inactive ingredients**  
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**Other information**  
 ■ Store at controlled room temperature 59°- 86°F (15°-30° C)



## APF FOAM with Xylitol Mint Parfait

Acidulated  
Phosphate Fluoride  
Treatment Foam  
1.23% Fluoride Ion

**GLUTEN FREE**

1 minute or 4 minute  
Treatment



4.4 fl.oz. (130 ml)

Shake well before  
each use

INVERT CAN  
COMPLETELY  
AND DEPRESS  
NOZZLE  
TO DISPENSE



Manufactured by:  
**DHARMA**  
 RESEARCH, INC.  
[WWW.DHARMARESEARCH.COM](http://WWW.DHARMARESEARCH.COM)  
 5220 N.W. 72 Avenue  
 Unit 15, Miami, FL 33166  
**1-877-833-3725**

Re-order#: **56-00102**



**MADE IN USA**

Store at a controlled room temperature 59°-86°F (15°-30° C)

### IONITE APF FOAM

sodium fluoride aerosol, foam

#### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:53045-252
<b>Route of Administration</b>	DENTAL, TOPICAL, ORAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.5498 g in 126 g

## Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
WATER (UNII: 059QF0KO0R)	
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XYLITOL (UNII: VCQ006KQ1E)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
TROLAMINE (UNII: 9O3K93S3TK)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT (Mint Parfait)	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-252-44	126 g in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/22/2013	

**Labeler** - Dharma Research, inc. (078444642)

**Registrant** - Dharma Research, inc. (078444642)

## Establishment

Name	Address	ID/FEI	Business Operations
Dharma Research, inc.		078444642	manufacture(53045-252)