

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](#).

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#53045-251-44



APF FOAM
with Xylitol
Concord Grape

Acidulated
Phosphate Fluoride
Treatment Foam
1.23% Fluoride Ion

GLUTEN FREE

1 minute or 4 minute
Treatment



4.4 fl.oz. (130 ml)

MADE IN USA

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.

Warnings

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- Contents under pressure.
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- Do not puncture or incinerate container. Do not spray toward open flame.
- For Professional Use Only.

Directions

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Inactive ingredients

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

Other information

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

Shake well before each use

INVERT CAN COMPLETELY AND DEPRESS NOZZLE TO DISPENSE



Manufactured by:
DHARMA
RESEARCH, INC.
WWW.DHARMARESEARCH.COM
5220 N.W. 72 Avenue
Unit 15, Miami, FL 33156
1-877-833-3725

Re-order#: **56-00101**



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IONITE APF FOAM

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53045-251
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	1.5498 g in 126 g

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
WATER (UNII: 059QF0K00R)	
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	GRAPE (Concord Grape)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-251-44	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(53045-251)