

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# 53045-250-44



APF FOAM
with Xylitol
Bubble Gum

Acidulated
Phosphate Fluoride
Treatment Foam
1.23% Fluoride Ion

GLUTEN FREE

1 minute or 4 minute
Treatment



4.4 fl.oz. (130 ml)

Drug Facts

Active Ingredient 1.23% Fluoride Ion	Purpose Fluoride Treatment Foam
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Uses This is a prescription fluoride treatment foam used to help prevent dental decay.

Warnings

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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.
- For Professional Use Only.

Directions

- Remove can 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 insert 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 tray(s) and have patient expectorate.
- Instruct patient not to eat, drink or rinse for 30 minutes after treatment.

Inactive ingredients

Castor Oil, Decyl Glucoside, Distilled Water, Flavor, Hydrofluoric Acid, Phosphoric Acid, Poloxamer, Propellant A31, Sodium Benzoate, Sodium Lauryl 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 H.W. 72 Avenue
Unit 15, Miami, FL 33186
1-877-833-3725

Re-order#: **56-00100**



MADE IN USA

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

IONITE APF FOAM

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53045-250
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: 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	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-250-44	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(53045-250)

Revised: 4/2013

Dharma Research, inc.