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 Sulface, Sodium Saccharne, 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.
- 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.



MADE IN USA

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

IONITE APF FOAM

sodium fluoride aerosol, foam

Route of Administration

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:53045- 252	

DEA Schedule

DENTAL, TOPICAL, ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (FLUORIDE ION)	FLUORIDE ION	1.5498 g in 126 g

Inactive Ingredients		
Ingredient Name	Strength	
CASTOR OIL		
DECYL GLUCOSIDE		
WATER		
HYDROFLUORIC ACID		
PHO SPHORIC ACID		
SO DIUM BENZO ATE		
SO DIUM LAURETH SULFATE		
SACCHARIN SO DIUM		
XYLITOL		
POLOXAMER 407		
TROLAMINE		

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

P	ackaging			
#	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)	

Revised: 4/2013 Dharma Research, inc.