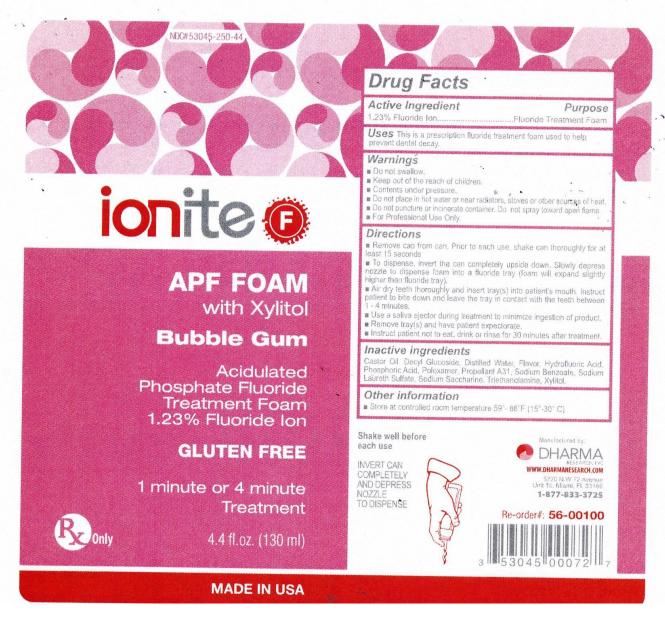
IONITE APF FOAM- sodium fluoride aerosol, foam Dharma Research, inc.

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.



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

IONITE APF FOAM

sodium fluoride aerosol, foam

P	roc	luct	Inf	orma	tion

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:Q80 VPU408O)	FLUORIDE ION	1.5498 g in 126 g

Inactive Ingredients				
Ingredient Name	Strength			
CASTOR OIL (UNII: D5340 Y2I9G)				
DECYL GLUCO SIDE (UNII: Z17H97EA6Y)				
WATER (UNII: 059QF0KO0R)				
HYDRO FLUO RIC ACID (UNII: RGL5YE86CZ)				
PHO SPHO RIC ACID (UNII: E4GA8884NN)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM LAURETH SULFATE (UNII: BPV390 UAP0)				
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.