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

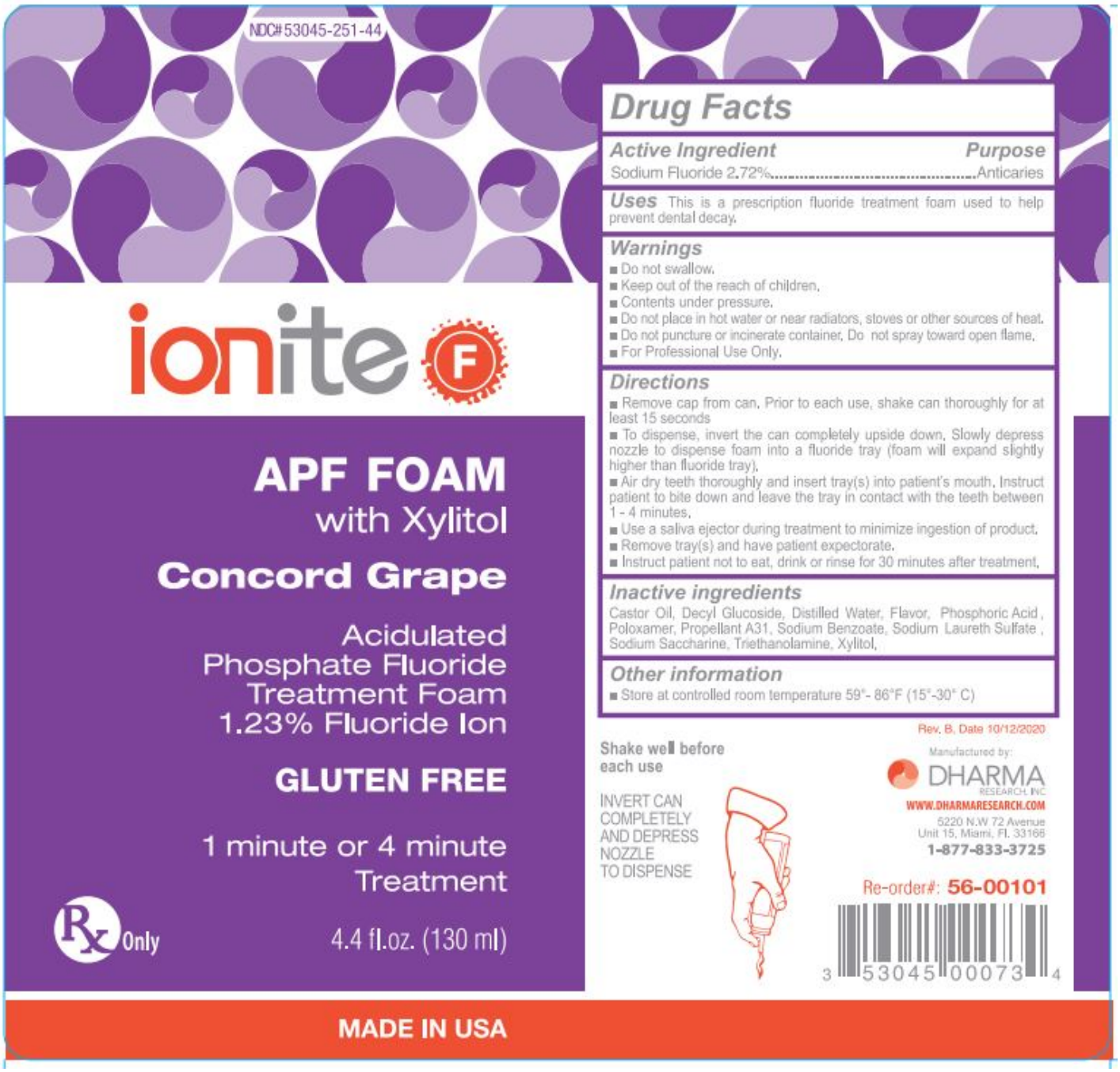
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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^{o}-86^{o}F (15^{o}-30^{o}C)



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: 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	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; Type 0: Not a Combination Product	04/22/2013	

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)

Revised: 10/2020 Dharma Research, inc.