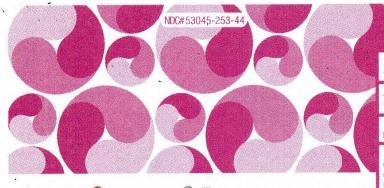
IONITE APF FOAM- sodium fluoride aerosol, foam Dharma Research, inc.

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.





APF FOAM with Xylitol

Strawberry Shortcake

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

Purpose

1,23% Fluoride Ion.

Fluoride Treatment Foam

Uses This is a prescription fluoride treatment foam used to help prevent dental decay.

Warnings

- Do not swallow.
- 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.
- w For Professional Use Only.

Directions

- 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 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, Poloxarner, Propellant A31, Sodium Benzoate, Sodium Laurath 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





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
LABEL

Item Code (Source)

NDC:530 45-

Route of Administration DENTAL, TOPICAL, ORAL DEA Schedule

Active Ingredient/Active Moiety

ш			
ı	Ingredient Name	Basis of Strength	Strength
ı	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 SPHO RIC ACID			
SO DIUM BENZO ATE			
SO DIUM LAURETH SULFATE			
SACCHARIN SO DIUM			
XYLITOL			
POLOXAMER 407			
TROLAMINE			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	STRAWBERRY (Strawberry Shortcake)	Imprint Code	
Contains			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:53045-253-44	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(53045-253)	

Revised: 4/2013 Dharma Research, inc.