

PURELIFE APF- sodium fluoride aerosol, foam
PureLife Dental

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](#).

Active Ingredient:

1.23% Fluoride Ion.

Available from 1.81% Sodium Fluoride and Hydrofluoric Acid.

Purpose:

Fluoride Preventative Treatment Foam.

Indications and Usage:

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

Warnings:

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 toward open flame. For Professional Use Only.

Instructions for Use

- 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 fluoride tray (foam will expand slightly higher than the 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 for 1-4 minutes.
- Use a saliva ejector during treatment to minimize ingestion of the product.
- Remove tray(s) and have patient expectorate.
- Instruct patient not to eat, drink or rinse for 30 minutes after treatment.

Inactive Ingredients

Distilled Water, Flavor, Hydrofluoric Acid, Isobutane Propane Propellant, Phosphoric Acid, Poloxamer, Sodium Benzoate, Sodium Laureth Sulfate, Sodium Saccharin, Triethanolamine, Xylitol.

Other Information:

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

Protect from freezing.

APF FOAM

FLUORIDE

with Xylitol

**Acidulated Phosphate
Fluoride Treatment Foam**
1.23% Fluoride Ion

- Gluten Free
- Rx Only

1 or 4 Minute Treatment

Net Wt. 4.4oz (125g)

CHERRY



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MANUFACTURED FOR
PureLife, LLC., Carson, CA 90810
www.PureLifeDental.com
877-777-3303

REORDER NO: 1830301

MADE IN USA | 99086301 Rev 11/13

Shake well before each use.

Invert can completely and depress nozzle to dispense



PURELIFE APF

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68987-021
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.5375 g in 125 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TROLAMINE (UNII: 9O3K93S3TK)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68987-021-12	125 g in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/27/2013	

Labeler - PureLife Dental (828690904)