TOPICAL FLUORIDE FOAM BUMBLE BEE BUBBLE GUM - acidulated phosphate fluoride aerosol Laclede, 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.

Package.Label Principal Display Panel

Topical Fluoride Foam

Acidulated Phosphate Fluoride Solution Containing 1.23% w/w Fluoride ion FOR PROFESSIONAL USE ONLY

Description: Topical Fluoride Foam is a flavored aqueous foaming solution of acidulated phosphate sodium fluoride with pH of 3.5 and a fluoride ion concentration of 1.23% w/w.

Active Ingredients: Sodium Fluoride and Hydrofluoric Acid (equivalent to 1.23% w/w Fluoride ion).

Inactive Ingredients: Purified Water, poloxamer 407, isobutane, poloxamer 234, phosphoric acid, sodium saccharin, flavor.

Fluoride Foam

NDC 5489-7507-17 NEW FOAM FORMULA!

FOR EFFECTIVE FLUORIDE TREATMENTS

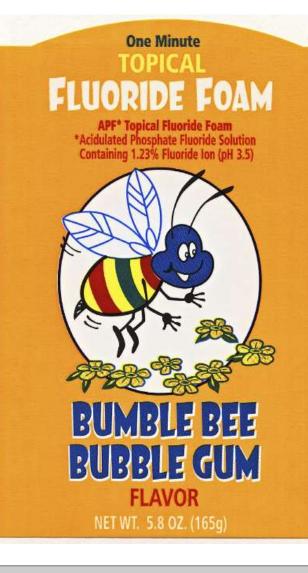
For topical application to aid in the protection against dental cares.

LACLEDE FLUORIDE FOAM
contains no thickening gels. The rich
thick foam is actually a liquid which
allows free movement of fluoride
ions to teeth and interproximal areas.
Because the fluoride is applied as a
foam, the total mass of fluoride in
the tray is actually less than gel
applications. This means a decreased
risk of accidental fluoride ingestion

US Patent No. 4,770,634

and systemic toxicity.

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MADE IN USA



CONTAINS NO FLUOROCARBONS

Federal law (USA) prohibits dispensing without prescription.

WARNING: Keep out of reach of children. Contents under pressure, Do not puncture or incinerate. Do not expose to heat. Store at room temperature.

FOR PROFESSIONAL USE ONLY

SHAKE WELL AND INVERT BOTTLE BEFORE DISPENSING

DIRECTIONS

- 1. Thoroughly clean teeth.
- 2. Fill application tray no more than one third full of Laclede Fluoride Foam.
- Dry teeth completely and insert tray(s) in mouth.
- 4. Have patient bite down for 1 minute.
- Remove tray(s) and have patient expectorate excess foam.
- Inform patient not to eat or drink for 30 minutes.

FORMULA: Sodium Fluoride, Hydrofluoric Acid (equivalent to 1.23% w/w F ion)

For Professional Use Only

TOPICAL FLUORIDE FOAM BUMBLE BEE BUBBLE GUM

acidulated phosphate fluoride aerosol

Product Information Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:54897-507 Route of Administration DENTAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride ion - UNII:Q80VPU408O)	Fluoride ion	10 mg in 1 g			
Hydrofluoric Acid (UNII: RGL5YE86CZ) (Fluoride ion - UNII:Q80VPU408O)	Fluoride ion	2.3 mg in 1 g			

Color	Score
Chana	
Shape	Size
Flavor BUBBLE GUM (Bu	ubble Gum Flavor) Imprint Code
Contains	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:54897-507-17	165 g in 1 BOTTLE			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		05/04/2000			

Labeler - Laclede, Inc. (098835994)

Revised: 3/2011 Laclede, Inc.