

DARBY APF STRAWBERRY- sodium fluoride aerosol, foam
DARBY APF MINT- sodium fluoride aerosol, foam
DARBY APF BUBBLE GUM- sodium fluoride aerosol, foam
Darby Dental Supply, LLC

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.

FLUORIDE FOAM

Strawberry

FOR PROFESSIONAL USE ONLY. A topical anti-caries preparation.

Directions For Use

1. Following prophylaxis treatment, fill 1/4 of tray with foam. 2. To dispense, shake can vigorously then invert applicator 180° downward to the bottom of the tray. 3. Insert tray, have patient bite down lightly for a minimum of 60 seconds, up to 4 minutes. 4. Remove tray and have patient expectorate excess. 5. Advise patient not to eat, drink or rinse for 30 minutes after the treatment.

Medical Ingredients

Fluoride Ions 1.23% w/w (from 2.72% w/w sodium fluoride).

Non-Medical Ingredients

Cocamidopropyl betaine, sodium phosphate monobasic, poloxamer 407, sucralose, xylitol, purified water, strawberry flavor.

Warnings

KEEP OUT OF REACH OF CHILDREN. For professional use only. Avoid spraying toward open flame. Store at room temperature. Do not expose to excessive heat over 104° F (40°C). Contents under pressure. Do not puncture or incinerate. Do not use if seal is broken.

To reorder: Call 800.645.2310 or visit darby.com

Distributed by: Darby Dental Supply, LLC, Jericho, NY 11753

NDC 66467-8003•2

Reorder# 9510050

1900196

Mint

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NDC 66467-8004•2

Reorder# 9510051

1900197

Bubble Gum

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Non-Medical Ingredients

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Distributed by: Darby Dental Supply, LLC, Jericho, NY 11753

NDC 66467-8005•2

Reorder# 9510052

1900198

PRINCIPAL DISPLAY PANEL - 125 g Can Label - Strawberry

darby
darby dental supply, llc

TOPICAL
FLUORIDE FOAM
2.72% TOPICAL SODIUM FLUORIDE FOAM
1.23% FLUORIDE IONS

130 Applications | 4.4 oz (125 g)

Strawberry



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SAFE PRINT AREA

MADE IN THE USA

PRINCIPAL DISPLAY PANEL - 125 g Can Label - Mint

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FLUORIDE FOAM
2.72% TOPICAL SODIUM FLUORIDE FOAM
1.23% FLUORIDE IONS

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SAFE PRINT AREA

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PRINCIPAL DISPLAY PANEL - 125 g Can Label - Bubble Gum

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NDC 66467-8005-2
Reorder # 9510052
1900198



SAFE PRINT AREA

MADE IN THE USA

DARBY APF STRAWBERRY

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66467-8003
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU4080)	SODIUM FLUORIDE	2.72 g in 100 g

Inactive Ingredients				
Ingredient Name				Strength
WATER (UNII: 059QF0KO0R)				
Sucralose (UNII: 96K6UQ3ZD4)				
Xylitol (UNII: VCQ006KQ1E)				
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)				
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)				
STRAWBERRY (UNII: 4J2TY8Y81V)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
Product Characteristics				
Color	WHITE		Score	
Shape			Size	
Flavor	STRAWBERRY		Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66467-8003-2	125 g in 1 CAN; Type 0: Not a Combination Product	10/29/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER			10/29/2019	

DARBY APF MINT				
sodium fluoride aerosol, foam				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66467-8004	
Route of Administration	DENTAL			
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)			SODIUM FLUORIDE	2.72 g in 100 g
Inactive Ingredients				
Ingredient Name				Strength

WATER (UNII: 059QF0KO0R)	
Sucralose (UNII: 96K6UQ3ZD4)	
Xylitol (UNII: VCQ006KQ1E)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
Peppermint Oil (UNII: AV092KU4JH)	
Spearmint Oil (UNII: C3M81465G5)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66467-8004-2	125 g in 1 CAN; Type 0: Not a Combination Product	10/29/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		10/29/2019	

DARBY APF BUBBLE GUM

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66467-8005
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	SODIUM FLUORIDE	2.72 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Sucralose (UNII: 96K6UQ3ZD4)	

Xylitol (UNII: VCQ006KQ1E)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
POLOXAMER 407 (UNII: TUF2IWW3M2)	

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:66467-8005-2	125 g in 1 CAN; Type 0: Not a Combination Product	10/29/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		10/29/2019	

Labeler - Darby Dental Supply, LLC (825137818)