

ACCLEAN FOAM FLUORIDE 60 SECOND APPLICATION- sodium fluoride aerosol, foam
Henry Schein

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.

ACCLEAN
Foam Fluoride
60 Second Application

General Information

Henry Schein, Inc.

Acclean Foam Fluoride 60 Second Application

Acidulated Phosphate Fluoride Foam (1.23% Fluoride Ion)

Contains:

Sodium fluoride in a proprietary acidulated phosphate flavored foam base. 1.23% fluoride ion is available from 2.72% sodium fluoride. Does not contain chlorofluorocarbon propellant.

Gluten free.

Indications

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

Warnings

Contains under pressure. Do not puncture or incinerate. Keep out of reach of children. Store between 50-80F. Keep from freezing. do not spray toward open flame.

Instructions For Use

- Prior to each use, shake can thoroughly for at least 15 seconds.
- To dispense, invert can completely upside down. Slowly depress nozzle to fill fluoride applicator tray (foam will expand slightly higher than fluoride tray).
- Tooth surface must be dry prior to inserting tray(s) in mouth.
- Insert tray(s) into mouth and have patient bite down for 1-4 minutes.
- Remove tray(s) and have patient expectorate.
- Advise patient not to eat, drink or rinse for 30 minutes after treatment.


Professional Use Only

Principal Display Panel


HENRY SCHEIN® 101-9360

ACCLEAN® Foam Fluoride

60 Second Application



Strawberry



Acidulated Phosphate Fluoride Foam
(1.23% Fluoride Ion)

Net. Wt. 4.4 oz. (125g)

Distributed by:
HENRY SCHEIN INC.
135 DURYEA ROAD
MELVILLE, NY 11747 USA
Made in U.S.A.

Indications: For topical application to aid in the protection against dental caries.

Contains: Sodium fluoride in a proprietary acidulated phosphate flavored foam base. 1.23% fluoride ion is available from 2.72% sodium fluoride. Does not contain chlorofluorocarbon propellant. Gluten free.

Warning: Contents under pressure. Do not puncture or incinerate. Keep out of reach of children. Store between 55-80 F. Keep from freezing. Do not spray toward open flame.


Instructions For Use:

- Prior to each use, shake can thoroughly for at least 15 seconds.
- To dispense, invert can completely upside down. Slowly depress nozzle to fill fluoride applicator tray (foam will expand slightly higher than fluoride tray).
- Teeth surface must be dry prior to inserting tray(s) in mouth.
- Insert tray(s) into mouth and have patient bite down for 1-4 minutes.
- Remove tray(s) and have patient expectorate.
- Advise patient not to eat, drink or rinse for 30 minutes after treatment.

Professional Use Only
NDC 0404-1701-44

Shake well before each use.

INVERT CAN COMPLETELY AND DEPRESS NOZZLE TO DISPENSE



1980103
Rev. 04/2019

Principal Display Panel

HENRY SCHEIN®

101-4580

ACCLEAN® Foam Fluoride

60 Second Application



Mint



Acidulated Phosphate Fluoride Foam
(1.23% Fluoride Ion)

Net. Wt. 4.4 oz. (125g)

Distributed by:
HENRY SCHEIN INC.
135 DURYEA ROAD
MELVILLE, NY 11747 USA
Made in U.S.A.

Indications: For topical application to aid in the protection against dental caries.

Contains: Sodium fluoride in a proprietary acidulated phosphate flavored foam base. 1.23% fluoride ion is available from 2.72% sodium fluoride. Does not contain chlorofluorocarbon propellant. Gluten free.

Warning: Contents under pressure. Do not puncture or incinerate. Keep out of reach of children. Store between 55-80 F. Keep from freezing. Do not spray toward open flame.

Instructions For Use:

- Prior to each use, shake can thoroughly for at least 15 seconds.
- To dispense, invert can completely upside down. Slowly depress nozzle to fill fluoride applicator tray (foam will expand slightly higher than fluoride tray).
- Tooth surface must be dry prior to inserting tray(s) in mouth.
- Insert tray(s) into mouth and have patient bite down for 1-4 minutes.
- Remove tray(s) and have patient expectorate.
- Advise patient not to eat, drink or rinse for 30 minutes after treatment.

**Professional
Use Only**
NDC 0404-1711-44

Shake well before each use.

**INVERT CAN
COMPLETELY
AND DEPRESS
NOZZLE
TO DISPENSE**



1960101
Rev. 04/2015

Principal Display Panel

HENRY SCHEIN®

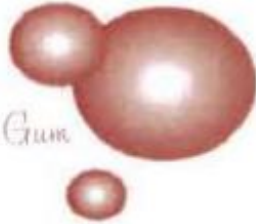
101-1102

ACCLEAN® Foam Fluoride

60 Second Application



Bubble Gum



Acidulated Phosphate Fluoride Foam
(1.23% Fluoride Ion)

Net. Wt. 4.4 oz. (125g)

Distributed by:
HENRY SCHEIN INC.
135 DURYEA ROAD
MELVILLE, NY 11747 USA
Made in U.S.A.

Indications: For topical application to aid in the protection against dental caries.

Contains: Sodium fluoride in a proprietary acidulated phosphate flavored foam base. 1.23% fluoride ion is available from 2.72% sodium fluoride. Does not contain chlorofluorocarbon propellant. Gluten free.

Warning: Contents under pressure. Do not puncture or incinerate. Keep out of reach of children. Store between 55-80 F. Keep from freezing. Do not spray toward open flame.

Instructions For Use:

- Prior to each use, shake can thoroughly for at least 15 seconds.
- To dispense, invert can completely upside down. Slowly depress nozzle to fill fluoride applicator tray (foam will expand slightly higher than fluoride tray).
- Tooth surface must be dry prior to inserting tray(s) in mouth.
- Insert tray(s) into mouth and have patient bite down for 1-4 minutes.
- Remove tray(s) and have patient expectorate.
- Advise patient not to eat, drink or rinse for 30 minutes after treatment.

**Professional
Use Only**
NDC 0404-1721-44

Shake well before each use.

**INVERT CAN
COMPLETELY
AND DEPRESS
NOZZLE
TO DISPENSE**



1906096
Rev. 04/2019

Principal Display Panel

HENRY SCHEIN®

101-4927

ACCLEAN® Foam Fluoride

60 Second Application



Grape



Acidulated Phosphate Fluoride Foam
(1.23% Fluoride Ion)

Net. Wt. 4.4 oz. (125g)

Distributed by:
HENRY SCHEIN INC.
135 DURYEA ROAD
MELVILLE, NY 11747 USA
Made in U.S.A.

Indications: For topical application to aid in the protection against dental caries.

Contains: Sodium fluoride in a proprietary acidulated phosphate flavored foam base. 1.23% fluoride ion is available from 2.72% sodium fluoride. Does not contain chlorofluorocarbon propellant. Gluten free.

Warning: Contents under pressure. Do not puncture or incinerate. Keep out of reach of children. Store between 55-80 F. Keep from freezing. Do not spray toward open flame.

Instructions For Use:

- Prior to each use, shake can thoroughly for at least 15 seconds.
- To dispense, invert can completely upside down. Slowly depress nozzle to fill fluoride applicator tray (foam will expand slightly higher than fluoride tray).
- Teeth surface must be dry prior to inserting tray(s) in mouth.
- Insert tray(s) into mouth and have patient bite down for 1-4 minutes.
- Remove tray(s) and have patient expectorate.
- Advise patient not to eat, drink or rinse for 30 minutes after treatment.

**Professional
Use Only**

NDC 0404-1731-44

Shake well before each use.

INVERT CAN
COMPLETELY
AND DEPRESS
NOZZLE
TO DISPENSE



1900100
Rev. 06/2013

Principal Display Panel

HENRY SCHEIN® 104-7344

ACCLEAN® Foam Fluoride

60 Second Application



Orange Cream

Acidulated Phosphate Fluoride Foam
(1.23% Fluoride Ion)

Net. Wt. 4.4 oz. (125g)

Distributed by:
HENRY SCHEIN INC.
135 DURYEA ROAD
MELVILLE, NY 11747 USA
Made in U.S.A.

Indications: For topical application to aid in the protection against dental caries.

Contains: Sodium fluoride in a proprietary acidulated phosphate flavored foam base. 1.23% fluoride ion is available from 2.72% sodium fluoride. Does not contain chlorofluorocarbon propellant. Gluten free.

Warning: Contents under pressure. Do not puncture or incinerate. Keep out of reach of children. Store between 55-80 F. Keep from freezing. Do not spray toward open flame.

Instructions For Use:

- Prior to each use, shake can thoroughly for at least 15 seconds.
- To dispense, invert can completely upside down. Slowly depress nozzle to fill fluoride applicator tray (foam will expand slightly higher than fluoride tray).
- Tooth surface must be dry prior to inserting tray(s) in mouth.
- Insert tray(s) into mouth and have patient bite down for 1-4 minutes.
- Remove tray(s) and have patient expectorate.
- Advise patient not to eat, drink or rinse for 30 minutes after treatment.

Professional Use Only
NDC 0404-1741-44

Shake well before each use.

INVERT CAN COMPLETELY AND DEPRESS NOZZLE TO DISPENSE



190102
Rev. 04/2019

ACCLEAN FOAM FLUORIDE 60 SECOND APPLICATION

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0404-1731
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0272 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
BETAINE (UNII: 3SCV180C9W)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-1731-44	125 g in 1 CANISTER; Type 0: Not a Combination Product	04/28/2021	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		04/28/2021		

ACCLEAN FOAM FLUORIDE 60 SECOND APPLICATION			
sodium fluoride aerosol, foam			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0404-1711
Route of Administration	DENTAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0272 g in 1 g	
Inactive Ingredients			
Ingredient Name	Strength		
BETAINE (UNII: 3SCV180C9W)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
XYLITOL (UNII: VCQ006KQ1E)			
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-1711-44	125 g in 1 CANISTER; Type 0: Not a Combination Product	04/28/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/28/2021	

ACCLEAN FOAM FLUORIDE 60 SECOND APPLICATION

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0404-1701
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.0272 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
BETAINE (UNII: 3SCV180C9W)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

		Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-1701-44	125 g in 1 CANISTER; Type 0: Not a Combination Product	04/28/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/28/2021	

ACCLEAN FOAM FLUORIDE 60 SECOND APPLICATION				
sodium fluoride aerosol, foam				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0404-1721	
Route of Administration	DENTAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0272 g in 1 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	POLOXAMER 407 (UNII: TUF2IVW3M2)			
	XYLITOL (UNII: VCQ006KQ1E)			
	SUCRALOSE (UNII: 96K6UQ3ZD4)			
	SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)			
	BETAINE (UNII: 3SCV180C9W)			
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	BUBBLE GUM	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-1721-44	125 g in 1 CANISTER; Type 0: Not a Combination Product	04/28/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/28/2021	

ACCLEAN FOAM FLUORIDE 60 SECOND APPLICATION

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0404-1741
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0272 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLOXAMER 407 (UNII: TUF2IVW3M2)	
XYLITOL (UNII: VCQ006KQ1E)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
BETAINE (UNII: 3SCV180C9W)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	ORANGE (Cream)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-1741-44	125 g in 1 CANISTER; Type 0: Not a Combination Product	04/28/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

unapproved drug other		04/28/2021	
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Labeler - Henry Schein (012430880)

Revised: 4/2021

Henry Schein