

**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.*

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**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®**

104-7344

## ACCLEAN® Foam Fluoride

*60 Second Application*



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**



1905102  
Rev. 04/2019

# ACCLEAN®

## FLUORIDE FOAM 1.23% APF\*

**1 Minute  
Application,  
Bubble Gum**



NET WT: 4.4 FL OZ (125 g)

by  HENRY SCHEIN®

**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. 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:** Shake well before each use. **INVERT CAN COMPLETELY AND DEPRESS NOZZLE TO DISPENSE.**

**REF** 101-1102  
1900099 [01]  
NDC 0404-1721-44

*Distributed by:*  
**Henry Schein Inc.**  
135 Duryea Road  
Melville, NY 11747 USA

REV. 2022/05

**MADE IN USA**

\*Acidulated Phosphate Fluoride Foam

# ACCLEAN®

## FLUORIDE FOAM 1.23% APF\*

**1 Minute  
Application,  
Grape**



NET WT: 4.4 FL OZ (125 g)

by  HENRY SCHEIN®

**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. 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:** Shake well before each use. **INVERT CAN COMPLETELY AND DEPRESS NOZZLE TO DISPENSE.**

**REF** 101-4927  
1900100 [01]  
NDC 0404-1731-44

*Distributed by:*  
Henry Schein Inc.  
135 Duryea Road  
Melville, NY 11747 USA

REV. 2022/05

**MADE IN USA**

\*Acidulated Phosphate Fluoride Foam

# ACCLEAN®

## FLUORIDE FOAM 1.23% APF\*

**1 Minute  
Application,  
Strawberry**



NET WT: 4.4 FL OZ (125 g)

by  HENRY SCHEIN®

**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. 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:** Shake well before each use. **INVERT CAN COMPLETELY AND DEPRESS NOZZLE TO DISPENSE.**

**REF** 101-9350  
1900103 [01]  
NDC 0404-1701-44

*Distributed by:*  
**Henry Schein Inc.**  
135 Duryea Road  
Melville, NY 11747 USA

REV. 2022/05

**MADE IN USA**

\*Acidulated Phosphate Fluoride Foam

# ACCLEAN®

**FLUORIDE  
FOAM**  
1.23% APF\*

**1 Minute  
Application,  
Mint**



NET WT: 4.4 FL OZ (125 g)

by  HENRY SCHEIN®

**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. 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:** Shake well before each use. **INVERT CAN COMPLETELY AND DEPRESS NOZZLE TO DISPENSE.**

REF 101-4580

1900101 [01]

NDC 0404-1711-44

REV. 2022/05

*Distributed by:*

**Henry Schein Inc.**

135 Duryea Road

Melville, NY 11747 USA

**MADE IN USA**

\*Acidulated Phosphate Fluoride Foam

**ACCLEAN FOAM FLUORIDE 60 SECOND APPLICATION**

sodium fluoride aerosol, foam

### Product Information

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

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

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

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0404-1711
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<b>Route of Administration</b>	DENTAL
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### Active Ingredient/Active Moiety

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

### Inactive Ingredients

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

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### 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

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

### Active Ingredient/Active Moiety



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

### Inactive Ingredients

Ingredient Name	Strength
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS</b> (UNII: KH7I04HPUU)	
<b>POLOXAMER 407</b> (UNII: TUF2IWW3M2)	
<b>BETAINE</b> (UNII: 3SCV180C9W)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	STRAWBERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0404-1721
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>POLOXAMER 407</b> (UNII: TUF21VW3M2)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS</b> (UNII: KH7I04HPUU)	
<b>BETAINE</b> (UNII: 3SCV180C9W)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BUBBLE GUM	<b>Imprint Code</b>	
<b>Contains</b>			

## 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

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

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>POLOXAMER 407</b> (UNII: TUF21VW3M2)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS</b> (UNII: KH7I04HPUU)	
<b>BETAINE</b> (UNII: 3SCV180C9W)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ORANGE (Cream)	<b>Imprint Code</b>	
<b>Contains</b>			

### 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	03/31/2023

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/28/2021	03/31/2023

**Labeler** - Henry Schein (012430880)

Revised: 10/2023

Henry Schein