

**ACCLEAN - sodium fluoride gel, dentifrice**  
**Henry Schein 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](#).*

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**Drug Facts**

Other Ingredients - Purified water, glycerin, Xylitol and other sweeteners, Contains F D and C Blue No. 1

Active Ingredient: Sodium Fluoride 1.1%

(0.5% Fluoride Ion)

Indications: Helps prevent dental caries and hypersensitivity

Directions: Adults and children six years of age and older should brush with Acclean Home Care Gel once at bedtime. Apply thin bead of gel to toothbrush and brush for at least one minute, making sure all tooth surfaces are covered.

Adults: expectorate thoroughly. Do not rinse, eat, or drink for at least 30 minutes after use. Children six years of age and older: expectorate and rinse thoroughly.

If recommended by your dentist professional, this product can be used in place of your regular toothpaste.

**WARNINGS: DO NOT SWALLOW.** To avoid ingestion, supervision is required while children are using this product.

Swallowing excessive amounts of fluoride could cause dental fluorosis.

**KEEP OUT OF REACH OF INFANTS AND CHILDREN.**

Enter section text here **PRECAUTIONS:** Federal (USA) Law prohibits dispensing without prescription. Store at controlled room temperature 68 - 77 F (20 - 25 C).

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Reorder #102-8016

NDC 0404-8016-02

Manufactured in the U.S.A.

Distributed by:  
Henry Schein Inc.  
Melville, NY 11747  
U.S.A.

Rev. 4.04

 HENRY SCHEIN®

# ACCLEAN®

## HOME CARE GEL



**1.1% NEUTRAL  
SODIUM FLUORIDE**  
Contains Xylitol



**Mint**

Net Wt. 2 fl. oz. (56g)

**ACCLEAN**

sodium fluoride gel, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0404-8016
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	5 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0404-8016-02	56 g in 1 TUBE		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved drug other		01/01/1997	

**Labeler** - Henry Schein Inc. (012430880)

Revised: 7/2013

Henry Schein Inc.