

ACCLEAN PLUS - 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](#).

Inactive Ingredients

Purified Water, Glycerin, Carboxymethyl Cellulose, Xylitol, Sodium Benzoate, Titanium Dioxide, Sucralose, Casein, Sodium Phosphate Monobasic, Calcium Hydroxyapatite, Silica, Sodium Phosphate Dibasic, Flavor.

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[®] Plus Home Care Gel once at bedtime (or as directed by physician or dentist). Apply a 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, drink or eat for at least 30 minutes after use. CHILDREN SIX YEARS OF AGE AND OLDER: Expectorate and rinse thoroughly. If recommended by your dental professional, this product can be used in place of your regular toothpaste. Read all instructions and prescribing information before using this product.

Warning

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 CHILDREN AND INFANTS. This product should not be used by individuals with milk allergies.

Precautions

Federal (U.S.A.) Law prohibits dispensing without prescription. Store at controlled room temperature 68° - 77° F (20°C - 25°C).

Reorder # 112-6918
Reorder # 112-6919

Distributed by (In US Only) HENRY SCHEIN INC.
135 DURYEA ROAD
Melville, NY 11747 USA

Package Label

NDC 0404-6918-01

HENRY SCHEIN®
ACCLEAN® PLUS

HOME CARE GEL

HENRY SCHEIN SEAL OF EXCELLENCE®

1.1% NEUTRAL SODIUM FLUORIDE

Contains MCH-C*

*(Micronized Calcium Hydroxyapatite & Casein)

MINT FLAVOR

Net Wt. 1.4 oz. (40g)

Rx Only

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(manufacturer) 135 DURYEA ROAD
Melville, NY 11747 USA
HENRY SCHEIN U.K. HOLDINGS LTD.
MEDCARE HOUSE, CENTURION CLOSE
GILLINGHAM BUSINESS PARK
GILLINGHAM, ME8 0SB U.K.

245496

Made in U.S.A.
Rev. 03/2014



+H65811269180J

NDC 0404-6919-01

HENRY SCHEIN®

ACCLEAN® PLUS

HOME CARE GEL

HENRY SCHEIN SEAL OF EXCELLENCE®

1.1% NEUTRAL SODIUM FLUORIDE

Contains MCH-C*

*(Micronized Calcium Hydroxyapatite & Casein)

BUBBLE GUM FLAVOR

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NDC 0404-6919-01

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Reorder # 112-6919

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MEDCARE HOUSE, CENTURION CLOSE
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245497

Made in U.S.A.
Rev. 03/2014



+H65811269190K

ACCLEAN PLUS
sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0404-6918
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	11 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
Carboxymethylcellulose (UNII: 05JZI7B19X)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Sucralose (UNII: 96K6UQ3ZD4)	
Casein (UNII: 48268V50D5)	
Sodium Phosphate, Monobasic (UNII: 3980JIH2SW)	
Tribasic Calcium Phosphate (UNII: 91D9GV0Z28)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Sodium Phosphate, Dibasic (UNII: GR686LBA74)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-6918-01	40 g in 1 TUBE; Type 0: Not a Combination Product	04/15/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/15/2014	

ACCLEAN PLUS

sodium flouride gel, dentifrice

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XYLITOL (UNII: VCQ006KQ1E)	
Carboxymethylcellulose (UNII: 05JZI7B19X)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Sucralose (UNII: 96K6UQ3ZD4)	
Casein (UNII: 48268V50D5)	
Sodium Phosphate, Monobasic (UNII: 3980JIH2SW)	
Tribasic Calcium Phosphate (UNII: 91D9GV0Z28)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Sodium Phosphate, Dibasic (UNII: GR686LBA74)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

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

Establishment

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	manufacture(0404-6918, 0404-6919)

Revised: 11/2018

Henry Schein, Inc.