**ACCLEAN ANTI-CAVITY SENSITIVITY RELIEF- potassium nitrate, sodium fluoride paste, 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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**ACCLEAN™ Prescription Strength Anti-Cavity Toothpaste for Sensitivity Relief**

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Acclean Prescription Strength Anti-Cavity Toothpaste for Sensitivity Relief safely and effectively. See full prescribing information.
Acclean Prescription Strength Anti-Cavity Toothpaste for Sensitivity Relief with 1.1% Sodium Fluoride, 5% Potassium Nitrate for oral use

## INDICATIONS AND USAGE

Acclean Prescription Strength Anti-Cavity Toothpaste for Sensitivity Relief is indicated for use as part of a professional program for the prevention and control of dental caries. (1)

## DOSAGE AND ADMINISTRATION

- Apply a thin ribbon or pea-sized amount of Acclean Prescription Strength Anti-Cavity Toothpaste for Sensitivity Relief to a toothbrush and brush thoroughly on all tooth surfaces for at least one minute. (2)
- After use, adults should expectorate. For best results, do not eat, drink, or rinse for 30 minutes. Children, age 12-16, should expectorate after use and rinse mouth thoroughly. (2)
- Children under 12 years of age should consult a dentist or doctor.
- Use twice daily as your normal dentifrice or as directed by your dental professional. (2)

## DOSAGE FORMS AND STRENGTHS

Acclean Prescription Strength Anti-Cavity Toothpaste for Sensitivity Relief Mint Flavor: Green toothpaste containing 1.1% Sodium Fluoride, 5% Potassium Nitrate (Mint). (3)

## CONTRAINDICATIONS

Do not use in children under 6 years of age unless recommended by a dentist or physician. (4)

## WARNINGS AND PRECAUTIONS

- **DO NOT SWALLOW. (5)**
- **Keep out of reach of children under 12 years of age.** If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away. (5)
- Repeated ingestion of high levels of fluoride may cause dental fluorosis. (5)
- Do not use this product longer than 4 weeks unless recommended by a dentist or

physician. (5)

**ADVERSE REACTIONS**

Allergic reactions and other idiosyncrasies have rarely been reported. (6)

**To report SUSPECTED ADVERSE REACTIONS, contact your Henry Schein Dental representative.**

**FULL PRESCRIBING INFORMATION: CONTENTS***


* Sections or subsections omitted from the full prescribing information are not listed.

## 1 INDICATIONS AND USAGE

Acclean Prescription Strength Anti-Cavity Toothpaste for Sensitivity Relief is indicated for use as part of a professional program for the prevention and control of dental caries.

## 2 DOSAGE AND ADMINISTRATION

- Follow these instructions or use as instructed by a dental professional.
- Adults and children age 12 or older, apply a thin ribbon or pea-sized amount of Acclean Prescription Strength Anti-Cavity Toothpaste for Sensitivity Relief to a toothbrush and brush thoroughly on all tooth surfaces for at least one minute.

After use:

- Adults should expectorate. For best results, do not eat, drink, or rinse for 30 minutes.
- Children, age 12 to 16, should expectorate after use and rinse mouth thoroughly.
- Use twice daily as your normal dentifrice or as directed by your dental professional.

## 3 DOSAGE FORMS AND STRENGTHS

Acclean Prescription Strength Anti-Cavity Toothpaste for Sensitivity Relief: Green toothpaste containing 1.1% Sodium Fluoride, 5% Potassium Nitrate (Mint). (3)

## 4 CONTRAINDICATIONS

Do not use in children under 12 years of age unless recommended by a dentist or physician.

## 5 WARNINGS AND PRECAUTIONS

**DO NOT SWALLOW.**

- **Keep out of reach of children under 12 years of age.** If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.
- Prolonged daily ingestion may result in various degrees of dental fluorosis in children with developing dentition, especially if the water fluoridation exceeds 0.6 ppm, since younger children frequently cannot perform the brushing process without significant swallowing.
- Use in children under age 6 years requires special supervision to prevent repeated swallowing of toothpaste which could cause dental fluorosis.
- Read directions carefully before using.
- Keep out of reach of infants and children.
- Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.
- See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or physician.

## 6 ADVERSE REACTIONS

Allergic reactions and other idiosyncrasies have rarely been reported.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Pregnancy Category B

It has been shown that fluoride crosses the placenta of rats, but only 0.01% of the amount administered is incorporated in fetal tissues. Animal studies (rats, mice, rabbits) have shown that fluoride is not a teratogen. Maternal exposure to 12.2 mg fluoride/kg of body weight (rats) or 13.1 mg/kg of body weight (rabbits) did not affect the litter size or fetal weight and did not increase the frequency of skeletal or visceral malformations. There are no adequate or well controlled clinical studies in pregnant women. However, epidemiological studies conducted in areas with high levels of naturally fluoridated water showed no increase in birth defects. Heavy exposure to fluoride during in utero development may result in skeletal fluorosis which becomes evident in childhood.

### 8.3 Nursing Mothers

It is not known if fluoride is excreted in human milk. However, many drugs are excreted in milk, and caution should be exercised when products containing fluoride are administered to a nursing woman. Reduced milk production was reported in farm-raised fox when the animals were fed a diet containing a high concentration of fluoride (98-137 mg/kg of body weight). No adverse effects on parturition, lactation, or offspring were seen in rats administered fluoride up to 5 mg/kg of body weight.

### 8.4 Pediatric Use

The use of Acclean Prescription Strength Anti-Cavity Toothpaste for Sensitivity Relief in children age 6-16 as a caries preventive is supported by pioneering clinical studies with 1.1% sodium fluoride gels in mouth trays in students age 11-14 years conducted by Englander, et al.[2-4] Safety and effectiveness in pediatric patients below the age of 6 years have not been established. Prescribing physicians and dentists should consider total fluoride exposure (dental care plus food, water, and other sources) when prescribing the product for use in children. Please refer to the CONTRAINDICATIONS and WARNINGS AND PRECAUTIONS sections.

### 8.5 Geriatric Use

Subjects referenced in clinical studies of 1.1% (w/v) sodium fluoride, included 15 percent age 65 and over, with 1 percent age 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger clients, but greater sensitivity of some older individuals cannot be ruled out. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in clients with impaired renal function. Because elderly clients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

## 10 OVERDOSAGE

Accidental ingestion of large amounts of fluoride may result in acute burning in the mouth and sore tongue. Nausea, vomiting, and diarrhea may occur soon after ingestion (within 30 minutes) and are accompanied by salivation, hematemesis, and epigastric cramping abdominal pain. These symptoms may persist for 24 hours. If less than 5 mg fluoride/kg body weight (i.e., less than 2.3 mg fluoride/lb body weight) have been ingested, give calcium (e.g., milk) orally to relieve gastrointestinal symptoms and observe for a few hours. If more than 5 mg fluoride/kg body weight (i.e., more than 2.3 mg fluoride/lb body weight) have been ingested, induce vomiting, give orally soluble calcium (e.g., milk, 5% calcium gluconate or calcium lactate solution) and immediately seek medical assistance. For accidental ingestion of more than 15 mg fluoride/kg of body weight (i.e., more than 6.9 mg fluoride/lb body weight), induce vomiting and admit immediately to a hospital facility.

## 11 DESCRIPTION

Acclean Prescription Strength Anti-Cavity Toothpaste for Sensitivity Relief is a self-applied

topical fluoride dentifrice containing 1.1% (w/w) sodium fluoride for the prevention and control of dental caries, and 5% (w/w) P otassium Nitrate for relief of tooth sensitivity.

**Sensitivity Relief:** Each gram contains 5 mg of fluoride ion in a neutral pH base, consisting of Cellulose Gum, D&C Yellow No. 10, FD&C Blue No. 1, Flavor, Glycerin, Mica (and) Titanium Dioxide, PEG/PPG-116/66 Copolymer, Potassium Nitrate, Silica, Sodium Lauryl Sulfate, Sodium Saccharin, Sorbitol, Water, Xylitol.

## 12 CLINICAL PHARMACOLOGY

A treatment dose (a thin ribbon) of Acclean Prescription Strength Anti-Cavity Toothpaste for Sensitivity Relief 5000 ppm sodium fluoride toothpaste contains 2.5 mg fluoride. A 4 oz. tube contains 566 mg fluoride.

Frequent topical applications to the teeth with preparations having a relatively high fluoride content increase tooth resistance to acid dissolution and enhance penetration of the fluoride ion into tooth enamel.

## 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a study conducted in rodents, no carcinogenesis was found in male and female mice and female rats treated with fluoride at dose levels ranging from 4.1 to 9.1 mg/kg of body weight. Equivocal evidence of carcinogenesis was reported in male rats treated with 2.5 and 4.1 mg/kg of body weight. In a second study, no carcinogenesis was observed in rats, males or females, treated with fluoride up to 11.3 mg/kg of body weight. Epidemiological data provide no credible evidence for an association between fluoride, either naturally occurring or added to drinking water, and risk of human cancer. Fluoride ion is not mutagenic in standard bacterial systems. It has been shown that fluoride ion has potential to induce chromosome aberrations in cultured human and rodent cells at doses much higher than those to which humans are exposed. In vivo data are conflicting. Some studies report chromosome damage in rodents, while other studies using similar protocols report negative results. Potential adverse reproductive effects of fluoride exposure in humans have not been adequately evaluated. Adverse effects on reproduction were reported for rats, mice, fox, and cattle exposed to 100 ppm or greater concentrations of fluoride in their diet or drinking water. Other studies conducted in rats demonstrated that lower concentrations of fluoride (5 mg/kg of body weight) did not result in impaired fertility and reproductive capabilities.

## 15 REFERENCES


1. American Dental Association, Council on Dental Therapeutics, Fluoride compounds, In: Accepted Dental Therapeutics, Ed. 40, Chicago, ADA, 405-407, (1984).
2. Englander HR, et al., Clinical Anticaries Effect of Repeated Topical Sodium Fluroide Applications by Mouthpieces, JADA, 75, 638-644, (1967).
3. Englander HR, et al., Residual Anticaries Effect of Repeated Topical Sodium Fluoride Applications by Mouthpieces, JADA, 78, 783-787 (1969).
4. Englander HR, et al: JADA, 83:354-358, 1971.

## 16 HOW SUPPLIED/STORAGE AND HANDLING

4 oz. (113.4g) net wt. tube

Acclean Prescription Strength Anti-Cavity Toothpaste for Sensitivity Relief NDC 0404 0174 04

Store at controlled room temperature 15°-30° C (59°-86° F)

**Rx Only**

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

753212700 R:0 01/24SN

**Principal Display Panel – 113.4 g Carton Label**

**ACCLEAN™**

PRESCRIPTION STRENGTH
**ANTI-CAVITY**
**TOOTHPASTE**
1.1 % Sodium Fluoride
5000 PPM
5% Potassium Nitrate

***For***
***Sensitivity***
***Relief,***
***Mint***

NET WT: 4 FL OZ (113.4g)

**by HENRY SCHEIN®**

ACCLEAN™

by HENRY SCHEIN®

**INDICATIONS AND USAGE:**
Prescription fluoride toothpaste for use as part of a professional program for the prevention and control of dental caries.

**ACTIVE INGREDIENTS:**
1.1% Sodium Fluoride, 5% Potassium Nitrate

**INACTIVE INGREDIENTS:** Cellulose Gum, D&C Yellow No. 10, FD&C Blue No. 1, Flavor, Glycerin, Mica (and) Titanium Dioxide, PEG/PPG-116/66 Copolymer, Silica, Sodium Lauryl Sulfate, Sodium Saccharin, Sorbitol, Water, Xylitol.

**DIRECTIONS FOR USE:**
This prescription toothpaste is recommended for adults and children 12 years of age and older. Children under 12 years of age: Consult a dentist or doctor. Use twice daily as your normal dentifrice or as directed by your dental professional.

1. Apply a thin ribbon or pea-sized amount of Acclean Prescription Strength Anti-Cavity Toothpaste for Sensitivity Relief to a toothbrush and brush thoroughly on all tooth surfaces for at least one minute.

2. After Use: Adults expectorate. For best results, do not eat, drink or rinse for 30 minutes. Children age 12-16, expectorate after use and rinse mouth thoroughly.

NOTE: Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or physician.

**WARNINGS AND PRECAUTIONS:**
DO NOT SWALLOW. Keep out of reach of children under 12 years of age. Read all instructions and prescribing information before using this product.

See package insert for additional information.

Store at controlled room temperature 15°-30°C (59°-86°F)

REF 570-3221
NDC 0404 0174 04 **Rx Only**

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

**MADE IN USA**

080520200 R:0 01/24CM

ACCLEAN™
Everyday Preventives for Healthy Patients
by HENRY SCHEIN®

ACCLEAN™

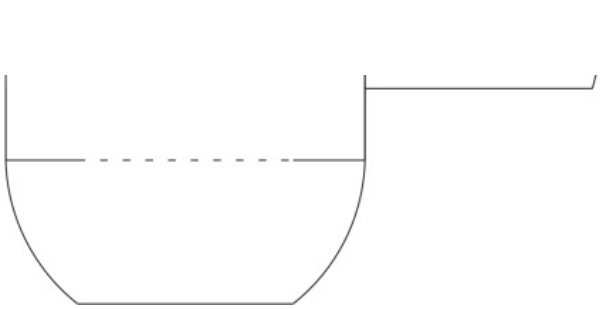
PRESCRIPTION STRENGTH
**ANTI-CAVITY TOOTHPASTE**
1.1% Sodium Fluoride
5000 PPM
5% Potassium Nitrate

***For Sensitivity Relief, Mint***

NET WT: 4 FL OZ (113.4g)

by HENRY SCHEIN®

ACCLEAN™
Everyday Preventives for Healthy Patients
by HENRY SCHEIN®



# ACCLEAN ANTI-CAVITY SENSITIVITY RELIEF

potassium nitrate, sodium fluoride paste, dentifrice

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0404-0174 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **POTASSIUM NITRATE** (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844) | POTASSIUM NITRATE | 5 g in 100 g |
| **SODIUM FLUORIDE** (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 1.1 g in 100 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED** (UNII: K679OBS311) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **Glycerin** (UNII: PDC6A3C0OX) | |
| **Mica** (UNII: V8A1AW0880) | |
| **Titanium Dioxide** (UNII: 15FIX9V2JP) | |
| **PEG/PPG-116/66 COPOLYMER** (UNII: JP0CK963E0) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **Sodium Lauryl Sulfate** (UNII: 368GB5141J) | |
| **Saccharin Sodium** (UNII: SB8ZUX40TY) | |
| **Sorbitol** (UNII: 506T60A25R) | |
| **Water** (UNII: 059QF0KO0R) | |
| **Xylitol** (UNII: VCQ006KQ1E) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | MINT (MINT) | **Imprint Code** | |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| | | | **Marketing Start** | **Marketing End** |

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0404-0174-04 | 1 in 1 CARTON | 01/30/2025 | |
| **1** | | 113.4 g in 1 TUBE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 01/30/2025 | |

## Labeler - Henry Schein, Inc. (012430880)

## Registrant - Den-Mat Holdings, LLC (809857704)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Den-Mat Holdings, LLC | | 809857704 | MANUFACTURE(0404-0174) |

Revised: 11/2024 Henry Schein, Inc.