

TRUGUARD 5000- sodium fluoride toothpaste paste, dentifrice
The Atlanta Dental Supply Company DBA Advanced Dental Products

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.

TruGuard 5000 Professional Cleaning System

TruGuard 5000 1.1% Sodium Fluoride Prescription Toothpaste

Rx Only

DESCRIPTION: Self-topical neutral fluoride dentifrice containing 1.1%(w/w) sodium fluoride for use as a dental caries preventive in adults and pediatric patients.

Active Ingredients: Sodium Fluoride 1.1%(w/w), Potassium Nitrate

Inactive Ingredients: Filtered Water, Sorbitol, Hydrated Silica, Glycerin, PEG, Carboxymethylcellulose, Dimethicone, Xylitol, Monosodium Phosphate, Titanium Dioxide, Mint Flavor, Sodium Saccharin.

CLINICAL PHARMACOLOGY: 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.

INDICATIONS AND USAGE: A dental caries preventive; for once daily self-applied topical use. It is well established that 1.1% sodium fluoride is safe and extraordinarily effective as a caries preventive when applied frequently with mouthpiece applicators. 1-4 TruGuard brand of 1.1% sodium fluoride in a squeeze tube is easily applied onto a toothbrush. This prescription dental cream should be used once daily in place of your regular toothpaste unless otherwise instructed by your dental professional. May be used whether or not drinking water is fluoridated, since topical fluoride cannot produce fluorosis. (See WARNINGS for exception.)

CONTRA INDICATIONS: Do not use in pediatric patients under age 6 years unless recommended by a dentist or physician.

WARNINGS: Prolonged daily ingestion may result in various degrees of dental fluorosis in pediatric patients under 6 years, especially if the water fluoridation exceeds 0.6 ppm, since younger pediatric patients frequently cannot perform the brushing process without significant swallowing. Use in pediatric patients under age 6 years requires special supervision to prevent repeated swallowing of the cream which could cause dental fluorosis. Read directions carefully before using. Keep out of reach of infants and children.

PRECAUTIONS: Not for systematic treatment. DO NOT SWALLOW.

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 bodyweight. 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 (5mg/kg of body weight) did not result in impaired fertility and reproductive capabilities.

Pregnancy: Pregnancy Category B. It has shown that fluoride crosses the placenta of rats, but only 0.01% of the amount administered is incorporated in fetal tissue. 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 of fetal weight and did not increase the frequency of skeletal or visceral malformations. Epidemiological studies conducted in areas with high levels of naturally fluoridated water showed no increase in birth defects, Heavy exposure to fluoride during utero development may result in skeletal fluorosis, which becomes evident in childhood.

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 product 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 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.

Pediatric Use: The use of TruGuard in pediatric age groups 6 to 16 years 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. 2,3,4 Safety and effectiveness in pediatric patients below the age of 6 years have not been established. Please refer to the **CONTRA INDICATIONS** and **WARNINGS** sections.

ADVERSE REACTIONS: Allergic reaction and other idiosyncrasies have been rarely reported.

OVERDOSAGE: Accidental ingestion of large amounts of fluoride may result in acute burning of 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 of 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 emesis, 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.

DOSAGE AND ADMINISTRATION: Follow these instructions unless otherwise instructed by your dental professional: 1. Adults and pediatric patients 6 years of age or older, apply a thin ribbon of TruGuard to a toothbrush. Brush thoroughly once daily for two minutes, preferably at bedtime. 2. After use, adults expectorate. For best results, do not eat, drink or rinse for 30 minutes. Pediatric patients, age 6-16, expectorate after use and rinse mouth thoroughly.

Directions: Use As Directed
This prescription dentifrice is recommended for adults and pediatric patients 6 years and older.

- Apply a thin ribbon of TruGuard 5000 along the length of the toothbrush no more than "pea size" total dose. Brush for two minutes.
- After brushing: **ADULTS-** Expectorate; Expectorate; do not eat or drink for 30 minutes. **CHILDREN 6 YEARS OF AGE OR OLDER-**Expectorate Expectorate and rinse mouth with water.
- Use at bedtime in place of your regular toothpaste or as directed by your dental professional.

HOW SUPPLIED: 4 oz. (112 gm) net wt. tube

STORAGE: Store at controlled room temperature, 20-25°C (68-77°F).

NDC #: 71347-500-04

PRINCIPAL DISPLAY PANEL - 4 OZ. Tube Sodium Fluoride 1.1%(w/w), Potassium Nitrate Toothpaste

Rx Only

NDC 71347-500-04

TruGuard 5000

Professional Cleaning System

1.1% Neutral Sodium Fluoride 5000 ppm Toothpaste with 5% Potassium Nitrate. Sweetened with Xylitol. Does not Contain Sodium Lauryl Sulfate.

Net Wt. 4 oz. (112 G)

Distributed by:

Advanced Dental Products
P.O. Box 29279
Atlanta, GA 30359

Carton Label

Rx ONLY

Professional Cleaning System

TruGuard 5000

Contains **XYLITOL** to reduce drymouth

fresh mint relieves sensitivity

Net Wt. 4 oz. (112 g)

NDC 71347-093-04

1.1% Neutral Sodium Fluoride 5000 ppm Toothpaste with 5% Potassium Nitrate. Sweetened with Xylitol. Does not Contain Sodium Lauryl Sulfate.

Professional Cleaning System

TruGuard 5000 is a sodium fluoride dentifrice formulated for the treatment of patients best suited to receive single step additional fluoride incorporated into their everyday home oral care regimen. TruGuard 5000 also contains 5% potassium nitrate that will stop decay and sensitivity.

- Reduces Caries
- Relieves Hypersensitivity
- Reduces Plaque Formation
- Strengthens Tooth Enamel
- Control root surface caries
- Reduces Dry Mouth
- Provides Gentle Cleaning

Contains **XYLITOL** to reduce drymouth



(01)00371347008289

1.1% Neutral Sodium Fluoride 5000 ppm Toothpaste with 5% Potassium Nitrate. Sweetened with Xylitol. Does not Contain Sodium Lauryl Sulfate.

Rx ONLY

Professional Cleaning System

TruGuard 5000

Contains **XYLITOL** to reduce drymouth

fresh mint relieves sensitivity

Net Wt. 4 oz. (112 g)

NDC 71347-093-04

1.1% Neutral Sodium Fluoride 5000 ppm Toothpaste with 5% Potassium Nitrate. Sweetened with Xylitol. Does not Contain Sodium Lauryl Sulfate.

TruGuard 5000

1.1% Neutral Sodium Fluoride 5000 ppm Toothpaste with 5% Potassium Nitrate. Sweetened with Xylitol. Does not Contain Sodium Lauryl Sulfate.

INGREDIENTS

Active Ingredients:

1.1% Neutral Sodium Fluoride

5% Potassium Nitrate

Xylitol

Other Ingredients:

Carboxymethylcellulose

Chlorhexidine, 0.1% (Hexachloro-4,1-cyclohexene-1,4-diene)

Fluorapatite, Titanium Dioxide, Zinc Oxide, Sodium Saccharin, Potassium Nitrate, Xylitol

Contains Xylitol

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Quadrant comment:
-877-997-7347

Advanced
Denture
Advanced Oral Products
Kalamazoo, MI 49001

TriGuard 5000 1.1% Sodium Fluoride Prescription Dental Cream

DESCRIPTION: Prescription topical fluoride dentifrice containing 1.1% (w/w) sodium fluoride for use as a dental caries preventive in adults and pediatric patients.

Active Ingredients: Sodium Fluoride 1.1% (w/w), Potassium Nitrate

Inert Ingredients: Fluoride Water, Sorbitol, Hydroxyethyl Cellulose, Glycerin, PEG, Carbonyl diurethane, Dextrinose, Xylitol, Monosodium Phosphate, Titanium Dioxide, Zinc Phosphate, Sodium Saccharin

CLINICAL PHARMACOLOGY: Frequent topical applications to the teeth with preparations having a relatively high fluoride content have been shown to reduce a 60% dissolution and enhance penetration of the fluoride into tooth enamel.
INDICATIONS AND USAGE: A dental caries preventive for once daily self-applied topical use. It is well established that 1.1% sodium fluoride is safe and substantially effective as a caries preventive when applied frequently with regular toothpaste applications. In TriGuard's case of 1.1% sodium fluoride in a sugar-free toothpaste, it may be used with either or without drinking water in fluoride, an optimal fluoride content product for fluoride. (See WARNINGS for exceptions.)

CONTRAINDICATIONS: Do not use on pediatric patients under 6 years of age unless recommended by a dental professional.

WARNINGS: Prolonged daily ingestion may result in various degrees of dental fluorosis in pediatric patients under 6 years, especially if the average fluoride exceeds 0.6 ppm, since younger pediatric patients frequently ingest fluoride in the following products that contain fluoride: Like in pediatric patients under age 6 years require special supervision to prevent repeated swallowing of the cream which could cause dental fluorosis. Read directions carefully before using. Keep out of reach of infants and children.

PRECAUTIONS: Not for use as a toothbrush. DO NOT SWALLOW.

Contraindications: In pregnancy, a 1-year study of fluoride in a study conducted in rat, no teratogenic effects were found in male and female rats and female rats treated with fluoride at dose levels ranging from 0.1 to 3.1 mg/kg of body weight. Equivalently, no teratogenic effects were reported in male rats treated with 2.5 and 4.1 mg/kg of body weight. In a second study, no teratogenic effects were observed in rats, males or females, treated with fluoride up to 11.7 mg/kg of body weight. Epidemiological data provide no credible evidence for an association between fluoride either naturally occurring or added to drinking water, as a result of human consumption. Fluoride ion is not a mutagenic agent and is not a carcinogen. It has been shown that fluoride ion has potential to reduce chromosome abnormalities 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 no chromosome damage. Potential adverse reproductive effects of fluoride exposure in humans have not been fully evaluated. Adverse effects on reproduction were reported for rats, mice, fox and other species at 100 ppm or higher concentrations of fluoride in their 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.
Pregnancy: Pregnancy Category D. It has been shown that fluoride crosses the placenta of rats, but only 33% of the amount administered is incorporated in fetal tissue. Dental status (teeth, nose, tibia) have shown that fluoride is not a teratogen. Maternal exposure to 12.2 mg fluoride/kg of body weight (ppm) or 12.1 mg/kg of body weight (ppm) did not affect the litter size of female rats and did not increase the frequency of skeletal or visceral malformations. Epidemiological studies conducted in areas with high levels of naturally fluoride water showed an increase in birth defects. Heavy exposure to fluoride during some development may result in skeletal fluorosis, which causes weakness in children.
Human: Fluorosis has not been observed in humans. However, many signs are associated with it, and caution should be exercised when product containing fluoride are administered to a nursing woman. Reduced milk production was reported in farm-raised females that were allowed to drink containing high concentrations of fluoride (50-127 mg/kg of body weight). No adverse effects on parturition, lactation or offspring were seen in rats administered fluoride up to 4 mg/kg of body weight.
Pediatric Use: The usual fluoride concentration in pediatric toothpaste (1.1% w/w) is safe as a dental caries preventive as supported by plaque-forming clinical studies in children up to 12 years of age. In a study conducted by Engleman, et al., (1974) safety and effectiveness of pediatric toothpaste below the age of 6 years have not been established. See contraindications.

CONTRAINDICATIONS AND WARNINGS: See above.

ADVERSE REACTIONS: Allergic reactions and other hypersensitivity reactions have been rarely reported.

OVERDOSAGE: Accidental ingestion of large amounts of fluoride may result in acute burning of the mouth and sore throat. Nausea, vomiting and diarrhea may occur soon after ingestion (within 20 minutes) and are accompanied by salivation, hematemesis and epigastric cramping abdominal pain. These symptoms may persist for 2 to 6 hours after 6 mg fluoride/kg of body weight (i.e., ingestion of 2.7 mg fluoride/kg body weight) have been reported, given orally (e.g., milk) only to relieve gastrointestinal symptoms and also for a few hours. If fluoride 6 mg/kg body weight (i.e., more than 2.7 mg fluoride/kg body weight) have been ingested, induce emesis, give orally active carbon (e.g., milk) 0.5 g/kg body weight.

Calcium lactate solution and immediately seek medical assistance. For a accidental ingestion of more than 10 mg fluoride/kg of body weight (i.e., more than 6.3 mg fluoride/kg body weight), milk or water may be administered immediately to a large child orally.
DOSEAGE AND ADMINISTRATION: Refer to the directions on the label. Use as directed by your dental professional. 1. Adults and pediatric patients 6 years of age or older, apply 6 to 8 mm of TriGuard to a toothbrush. Brush thoroughly secondarily for 2 minutes, probably at bedtime. 2. Allow use of the preparation. For best results, do not eat, drink or rinse for 30 minutes. Pediatric patients, age 6-12, expectorate after use and rinse mouth thoroughly.
HOW SUPPLIED: 4.5 oz. (127 gm) net wt tube
NDC: 63702-561-04

STORAGE: Store at controlled room temperature, 20-25°C (68-77°F).

Is Only

REFERENCES: 1. Accepted Dental Therapeutics, Et al., 404, Chicago, 1966-67, 704. 2. Engleman HR, Keyes et al. JADA 76:620-444, 1967. 3. Engleman HR, et al. JADA 75:727-737, 1965. 4. Engleman HR, et al. JADA 82:264-262, 1971.

Tube Label

DRUG FACTS

Active Ingredients:
1.1% Neutral Sodium Fluoride, Potassium Nitrate

Inactive Ingredients: Filtered Water, Sorbitol, Hydrated Silica, Glycerin, PEG, Carboxymethylcellulose, Dimethicone, Xylitol, Monosodium Phosphate, Titanium Dioxide, Mint Flavor, Sodium Saccharin.

Indications:
TruGuard 5000 is a self-applied dentifrice for prevention of tooth decay, orthodontic decalcification and hypersensitivity.


Warnings:

- Do not swallow
- For topical use only
- As with all medications, keep out of reach of children

Directions: Use As Directed
This prescription dentifrice is recommended for adults and pediatric patients 6 years and older.

- Apply a thin ribbon of TruGuard 5000 along the length of the toothbrush no more than "pea size" total dose. Brush for two minutes.
- After brushing: **ADULTS-** Expectorate; do not eat or drink for 30 minutes. **CHILDREN 6 YEARS OF AGE OR OLDER-** Expectorate and rinse mouth with water.
- Use at bedtime in place of your regular toothpaste or as directed by your dental professional

Questions? Comments?
1-877-895-7341
Distributed by: Advance Dental Products
P.O. Box 29279, Atlanta, GA 30359



1.1% Neutral Sodium Fluoride 5000 ppm Toothpaste with 5% Potassium Nitrate.
Sweetened with Xylitol.
Does not Contain Sodium Lauryl Sulfate.

NDC 71347-500-01

Rx ONLY
Net Wt. 4oz. (112 G)

Rx ONLY
Net Wt. 4oz. (112 G)

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| TRUGUARD 5000 | | | |
| sodium fluoride toothpaste paste, dentifrice | | | |
| Product Information | | | |
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:71347-500 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) | SODIUM FLUORIDE | 1.1 g in 100 g |
| | POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844) | POTASSIUM NITRATE | 5.0 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |

Product Characteristics

| | | | |
|-----------------|-------------------|---------------------|--|
| Color | white | Score | |
| Shape | | Size | |
| Flavor | MINT (fresh mint) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:71347-500-04 | 1 in 1 BOX | 03/16/2023 | |
| 1 | | 112 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 | | 03/16/2023 | |

Labeler - The Atlanta Dental Supply Company DBA Advanced Dental Products (033505389)

Registrant - The Atlanta Dental Supply Company DBA Advanced Dental Products (033505389)