SODIUM FLOURIDE- sodium fluoride paste, dentifrice
AvKARE

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.

Sodium Flouride 1.1%
1.1% SODIUM FLOURIDE Prescription Dental Toothpaste

Sodium Fluoride 1.1%

1.1% Sodium Fluoride Prescription Dental Toothpaste

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 Ingredient

Sodium fluoride 1.1% (w/w).

Inactive Ingredients

Dicalcium Phosphate, FD&C Blue No. 1, Flavor, Glycerin, Hydrated Silica, Purified Water, Sodium Benzoate, Sodium Lauryl Sulfate, Sorbitol, Spearmint Flavor, Titanium Dioxide, Xanthan Gum, Xylitol

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 Sodium

Fluoride 1.1% 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.)

CONTRAINDICATIONS

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 age 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 dental cream which could cause dental fluorosis. Read directions carefully

before using.

KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

PRECAUTIONS

General

Not for systemic 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 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 has 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.

Pregnancy

Teratogenic Effects

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 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 or fetal weight and did not increase the frequency of skeletal or visceral malformations. There are no adequate and well-controlled 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.

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.

Pediatric Use

The use of Sodium Fluoride 1.1% toothpaste 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 CONTRAINDICATIONS and WARNINGS sections.

Geriatric Use

Of the total number of subjects in clinical studies of 1.1% (w/v) sodium fluoride, 15 percent were 65 and over, while 1 percent were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, 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 patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

Allergic reactions and other idiosyncrasies have been rarely reported.

You should call your doctor, or dental professional for medical advise about serious adverse events. To report a serious adverse event or obtain product information, contact AvKARE at 1-855-361-3993 or FDA at 1-800-FDA-1088 (Toll Free).

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.

A treatment dose (a thin ribbon) of Sodium Fluoride 1.1% toothpaste contains 2.5 mg fluoride. A 1.8 oz. tube contains

255 mg fluoride.

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 Sodium Fluoride 1.1% toothpaste 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.

HOW SUPPLIED

1.8 oz. (51 g) net wt. tube

NDC# 42291-741-51

STORAGE

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

KEEP THIS PRODUCT OUT OF REACH OF CHILDREN

Rx Only

REFERENCES

1. American Dental Association, Council on Dental Therapeutics, Fluoride compounds, In: Accepted Dental Therapeutics,

Ed. 40, Chicago, ADA, 405-407 (1984).

2. H.R. Englander et al., Clinical Anticaries Effect of Repeated Topical Sodium Fluoride Applications by Mouthpieces,

JADA, 75, 638-644 (1967).

3. H.R. Englander, et al., Residual Anticaries Effect of Repeated Topical Sodium Fluoride Applications by Mouthpieces,

JADA 78, 783-787 (1969).

4. H.R. Englander HR et al., Incremental Rates of Dental Caries After Repeated Topical Sodium Fluoride Applications in

Children With Lifelong Consumption of Fluoridated Water, JADA, 82, 354-358, (1971).

Manufactured for:

AvKare

Pulaski, TN 38478

www.avkare.com

AV 08/22

PRINCIPAL DISPLAY PANEL - 51 g Tube Carton

Spearmint Rx Only NDC 42291-741-51

Sodium Fluoride 1.1%

1.1% SODIUM FLUORIDE Prescription Dental Toothpaste

5000 ppm Fluoride Plus Mild Cleaning System

NET WT. 1.8 OZ. (51 g)

Description: Self-topical neutral 1.1% sodium fluoride for use as a dental caries preventative in adults and pediatric patients.

Directions for daily use (unless otherwise instructed by your dental professional):

1. Adults and pediatric patients 6 years of age or older, apply a thin ribbon of Sodium Fluoride 1.1% to toothbrush. Brush thoroughly once daily for two minutes preferably at bedtime (or as directed).
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.

This prescription dental toothpaste may be used daily in place of your regular toothpaste based on the recommendation of your dental professional.

Precautions: DO NOT SWALLOW.

KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

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

To report a serious adverse event or obtain product information, call 1-855-361-3993.

See package insert for full product information.

Manufactured for:

AvKARE

Pulaski, TN 38478

www.avkare.com

AV 04/22 SF422

3 42291 74151 5

SODIUM FLOURIDE

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42291-741
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SPEARMINT (UNII: J7I2T6IV1N)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	blue (viscous)	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42291-741-51	1 in 1 CARTON	09/20/2019	
1		53.2 mL 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		09/20/2019	

Labeler - AvKARE (796560394)

Revised: 1/2024 AvKARE