NEUTRAL SODIUM FLUORIDE- sodium fluoride rinse
Sancilio & Company 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.

Neutral Sodium Fluoride 0.2%

Dental Rinse

DESCRIPTION

Neutral Sodium Fluoride 0.2% Dental Rinse is a grape flavored, neutral, aqueous solution containing no alcohol.

ACTIVE INGREDIENT: Sodium Fluoride 0.2% (w/v).

INACTIVE INGREDIENTS: Purified water, Glycerin, Xylitol, Propylene Glycol, Natural Grape Type Flavor, Methylparaben, Sucralose, Propylparaben.

CLINICAL PHARMACOLOGY

Topical application of sodium fluoride increases tooth resistance to acid dissolution, promotes remineralization, and inhibits the cariogenic microbial process.

INDICATIONS AND USAGE

For once weekly use as a dental caries preventative in pediatric patients.

WARNINGS

DO NOT SWALLOW. Keep out of reach of infants and children. Pediatric populations under the age of 12 years should be supervised in the use of this product. Patients under the age of 6 years require special supervision to prevent repeated swallowing of the rinse since they may frequently swallow large amounts while rinsing. Prolonged daily ingestion may result in dental fluorosis in patients under the age of 6 years, especially if water fluoridation exceeds 0.6 ppm. Read directions before using.

DOSAGE AND ADMINISTRATION

For caries – Adults and pediatric patients over 6 years of age, 2 teaspoonfuls (10 mL) once a week, preferably at bedtime after thoroughly brushing teeth, rinse vigorously around and between the teeth for one minute, then spit out. DO NOT SWALLOW. For maximum benefit, do not eat, drink, or rinse mouth for at least 30 minutes after treatment.

STORAGE

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

CONTRAINDICATIONS

Do not use in patients with dyaphagia. Do not use in pediatric patients under the age of 6 years unless recommended by a dentist or physician.

PRECAUTIONS

General

Not for systemic treatment. DO NOT SWALLOW.

CARCINOGENESIS, MUTAGENESIS, AND IMPAIRMENT OF FERTILITY

No carcinogenesis was observed in mice or female rats treated with fluoride at doses ranging from 4.1 to 9.1 mg/kg of body weight. Equivocal evidence of carcinogenesis was found in rats treated with 2.5 and 4.1 mg/kg of body weight. However, no carcinogenesis was reported in rats treated with fluoride up to 11.3 mg/kg of body weight. Epidemiological studies provide no credible evidence for an association between fluoride, either naturally occurring or added to drinking water, and risk of cancer. Fluoride ion is not mutagenic in standard bacterial systems. Fluoride ion has been associated with chromosome aberrations in cultured human and rodent cells at doses much higher than expected human exposures. Some in vivo studies report chromosome damage in rodent cells while other studies using similar doses report negative findings.

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 cattle exposed to 100 ppm or greater concentrations of fluoride in their diet or drinking water. Studies conducted in rats have shown that lower concentrations of fluoride (5 mg/kg of body weight) did not result in impaired fertility or reproductive capabilities.

PREGNANCY

Teratogenic Effects

Pregnancy Category B

Fluoride crosses the placenta in rats, but only 0.01% of the amount administered is incorporated in fetal tissue. Animal studies with rats, mice, and rabbits have demonstrated that fluoride is not teratogenic. Maternal exposure to 12.2 mg fluoride/kg of body weight in rats or 13.1 mg/kg of body weight in rabbits did not affect litter size or fetal weight and did not increase the frequency of skeletal or visceral malformations. No adequate or well-controlled studies have been conducted in pregnant women. Epidemiological studies conducted in areas with high levels of naturally occurring fluoridated water have shown no increase in birth defects. Heavy exposure during in utero development may result in skeletal fluorosis which becomes evident in childhood.

NURSING MOTHERS

It is not known whether fluoride is excreted in human milk. However, many drugs are excreted in human milk and caution should be exercised when fluoride products are administered to nursing women. Reduced milk production was reported in farm-raised fox when they 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 observed in rats administered fluoride up to 5 mg/kg of body weight.

PEDIATRIC USE

The use of Neutral Sodium Fluoride 0.2% Dental Rinse as a weekly caries preventative product in pediatric patients aged 6 to 16 years is supported by adequate and well-controlled clinical trials in students aged 6 to 12 years.1-3 Safety and efficacy in pediatric patients below the age of 6 years have not been established (refer to CONTRAINDICATIONS AND WARNINGS sections).

GERIATRIC USE

Of the total number of subjects considered in clinical trials using 1.1% (w/v) sodium fluoride, 15% were 65 years and older, while 1% were 75 years and older. Overall, no differences in safety or

efficacy were observed between these subjects and younger subjects. Other reported clinical data have not identified differences in responses between the elderly and younger patients but greater sensitivity in some older individuals cannot be ruled out. Fluoride is known to be substantially excreted by the kidney, and the risk of toxic reactions may be greater in patients with impaired renal function. Since elderly patients are more likely to have decreased renal function, care should be taken in dose selection. It may be useful to monitor renal function.

ADVERSE REACTIONS

In patients with mucositis, gingival tissues may be hypersensitive to flavor present in the formulation. Allergic reactions are rarely reported.

OVERDOSE

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/pound body weight) has been ingested, give calcium in the form of milk orally to relieve gastrointestinal symptoms and observe for a few hours. If more than 5 mg fluoride body weight (i.e., more than 2.3 mg fluoride/pound body weight) has been ingested, induce vomiting, administer orally soluble calcium in the form of milk, calcium gluconate or calcium lactate solution, and immediately seek medical assistance. For accidental ingestion of more than 15 mg fluoride/kg body weight (i.e., more than 6.9 mg fluoride/pound body weight) induce vomiting, and admit immediately to a hospital facility.

A treatment dose (10 mL) or two teaspoonfuls) of Neutral Sodium Fluoride 0.2% Dental Rinse contains approximately 9 mg of fluoride. One 16 fl oz bottle contains approximately 429 mg fluoride.

DOSAGE AND ADMINISTRATION

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HOW SUPPLIED

Plastic bottle with child-resistant closure containing 16 fl oz (473 mL).

STORAGE

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

REFERENCES

1. American Dental Association, Accepted Dental Therapeutics, Ed. 4, Chicago (1984):403.
2. Ibid., pp. 405-407.
3. L.W. Ripa, G.S. Leske, and A. Sposato, "Supervised Weekly Rinsing with a 0.2% Neutral NaF Solution: Final Results of a Demonstration Program after Six School Years," J. Pub. Health Dent. 1984;43:53-62.
4. W.S. Driscoll, et al., "Caries-Preventative Effects on School Children Daily and Weekly Fluoridate Mouthrinsing in a Fluoridated Community: Final Results after 30 Months," JADA 1982;105:1010-013.

Manufactured by:
Sancilio and Company
Riviera Beach, FL 33404

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

Made in USA

44946-1050-8

SCI

Developing Good Science
into Great Medicine

Neutral Sodium

Fluoride 0.2%

Dental Rinse
Alcohol Free

Rx Only

DO NOT SWALLOW

PROFESSIONAL

Grape Flavored
Colorless

16 fl oz (1 pt) (473 mL)

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16 fl oz (1 pt) (473 mL)

Neutral Sodium Fluoride 0.2% Dental Rinse

Description: Neutral Sodium Fluoride 0.2% Dental Rinse is a grape flavored, neutral, aqueous solution containing no alcohol. **Active Ingredients:** Sodium Fluoride 0.2% (w/v). **Inactive Ingredients:** Purified Water, Glycerin, Xylitol, Propylene Glycol, Natural Grape Type Flavor, Methylparaben, Sucralose, Propylparaben. **Clinical Pharmacology:** Topical application of sodium fluoride increases tooth resistance to acid dissolution, promotes remineralization, and inhibits the cariogenic microbial process. **Indications and Usage:** For once-weekly use as a dental caries preventative in pediatric patients. **Warnings:** Keep out of the reach of infants and children. **Dosage and Administration:** For caries - Adults and pediatric patients over 6 years, 2 teaspoonfuls (10 mL) once a week, preferably at bedtime after thoroughly brushing the teeth, rinse vigorously around and between the teeth for one minute, then expectorate. DO NOT SWALLOW. For maximum benefit, do not eat, drink or rinse mouth for at least 30 minutes after treatment. **Storage:** Store at Room Temperature 15-30° C (59-86°F). **See package insert for additional information.**

Manufactured by:
Sancilio and Company
Riviera Beach FL 33404 1-800-SCI-8711

LOT/EXP

Rev 01/23/13

NO VARNISH

DO NOT USE IF FOIL SEAL UNDER CAP IS BROKEN OR MISSING

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NEUTRAL SODIUM FLUORIDE

sodium fluoride rinse

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:44946-1050
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Xylitol (UNII: VCQ006KQ1E)	
Propylene glycol (UNII: 6DC9Q167V3)	
Methylparaben (UNII: A2I8C7HI9T)	
Sucralose (UNII: 96K6UQ3ZD4)	
Propylparaben (UNII: Z8IX2SC1OH)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44946-1050-0	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/2013	

Labeler - Sancilio & Company Inc (176681257)

Revised: 1/2013

Sancilio & Company Inc