NEUTRAL SODIUM FLUORIDE - sodium fluoride rinse
Sancilio & Company Inc

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.

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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

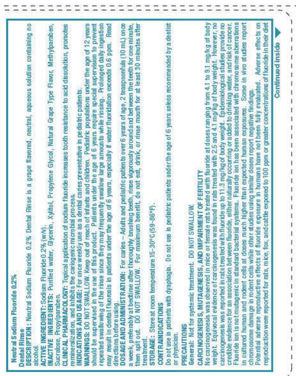
1. American Dental Association, Accepted Dental Therapeutics, Ed. 4, Chicago (1984):403.

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)