11 DESCRIPTION

Fluoridex® 0.63% Stannous Fluoride Daily Renewal Rinse brand of stannous fluoride is a stable, water-free concentrate containing 0.63% stannous fluoride for dilution to 0.1% stannous fluoride for use as a dental caries preventive. This is a fluoride treatment rinse, not a mouthwash. Read directions carefully before using.

Fluoridex 0.63% Stannous Fluoride Rinse is for professional use only.

12 CLINICAL PHARMACOLOGY

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

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.

16 HOW SUPPLIED/STORAGE AND HANDLING

Supplied as Mint flavor in 8.4 fl. oz. (248 ml)
Mint NDC 59883-004-01
Keep tightly closed when not in use.
Store at controlled room temperature 15°- 30° C (59°- 86° F).

Manufactured for
Den-Mat Holdings, LLC
1017 W. Central Ave.
Lompoc, CA 93436

752268000 R:1 12/18CM

Fluoridex® Stannous Fluoride Rinse (0.63% Concentrate)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Fluoridex Stannous Fluoride Daily Renewal Rinse safely and effectively. See full prescribing information.

Fluoridex Stannous Fluoride Rinse 0.63% concentrate for professional use

INDICATIONS AND USAGE

It is well established that a 0.1% stannous fluoride rinse is a convenient way to apply fluoride to the surfaces of teeth to aid in the prevention of decalcification and dental caries. This is accomplished by increasing the resistance of tooth surfaces to acid dissolution.

DOSAGE AND ADMINISTRATION

Adults and pediatric patients 12 years and older, use once a day or more often as directed by a dentist, following regular brushing and flossing. Pour the concentrated Fluoridex Stannous Fluoride Rinse to the 1/8 fl. oz. mark in the mixing cup (to the bottom mark). Add water to the 1 fl. oz. line and mix. This prepares a 0.1% stannous fluoride rinse. Use immediately after preparing the rinse. Place one half of the solution into the mouth and vigorously swish for one minute, then expectorate. Repeat the one-minute treatment with the remaining solution and expectorate. DO NOT SWALLOW the rinse. Pediatric patients under 12 years of age should be supervised in the use of this product to help minimize swallowing. For pediatric patients under 6 years of age, consult a dentist or physician.

DOSAGE FORMS AND STRENGTHS

Translucent – clear viscous liquid containing 0.63% Stannous Fluoride (Mint).

CONTRAINDICATIONS

None (may be used whether drinking water is fluoridated or not, since topical fluoride cannot produce fluorosis).

WARNINGS AND PRECAUTIONS

Warnings: As with all medications, keep out of reach of infants and children. Do not use before mixing with water. Read the directions carefully. Pediatric patients under 12 years of age should be supervised in the use of this product. For pediatric patients under 6 years of age, consult a dentist or physician. This product may produce temporary surface staining of teeth. Adequate brushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.

Precautions: DO NOT SWALLOW.

ADVERSE REACTIONS

Allergic reactions and other idiosyncrasies have rarely been reported.

To report SUSPECTED ADVERSE REACTIONS, contact DenMat at consumer@denmat.com

FULL PRESCRIBING INFORMATION: CONTENTS*

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

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1 INDICATIONS AND USAGE

It is well established that a 0.1% stannous fluoride rinse is a convenient way to apply fluoride to the surfaces of teeth to aid in the prevention of decalcification and dental caries. This is accomplished by increasing the resistance of tooth surfaces to acid dissolution.

2 DOSAGE AND ADMINISTRATION INSTRUCTIONS FOR GENERAL USE

Follow these instructions or use as instructed by a dental professional.

- Adults and pediatric patients 12 years and older, use once a day or more often as directed by a dentist, following regular brushing and flossing.
- Pour the concentrated Fluoridex 0.63% Stannous Fluoride Rinse into the mixing cup up to the 1/8 fl. oz. mark, add water to the 1 fl. oz. line, snap on the mixing cup over and shake well to mix the solution.
  - This prepares a 0.1% stannous fluoride rinse.
- Use immediately after preparing the rinse. Place one half of the solution into the mouth and vigorously swish for one (1) minute, then expectorate (spit out). DO NOT SWALLOW the rinse.
- Repeat the one-minute treatment with the remaining solution and expectorate.
- Pediatric patients under 12 years of age should be supervised in the use of this product to minimize swallowing.
- For pediatric patients under 6 years of age, do not use without consulting a dentist or physician first.

3 DOSAGE FORMS AND STRENGTHS

Translucent – clear viscous liquid containing 0.63% Stannous Fluoride (Mint).

4 CONTRAINDICATIONS

None (may be used whether drinking water is fluoridated or not, since topical fluoride cannot produce fluorosis).

5 WARNINGS AND PRECAUTIONS

- **DO NOT SWALLOW.**
- **Keep out of reach of infants and children.** If more than used for rinsing is accidently swallowed, get medical help or contact a Poison Control Center right away.
- DO NOT use before mixing with water.
- Use as directed by a dental professional.
- Read directions carefully before using.
- Pediatric patients under 12 years of age should be supervised in the use of this product.
- For pediatric patients under 6 years of age, consult a dentist or physician.
- This product may produce temporary surface staining of teeth. Adequate brushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.

6 ADVERSE REACTIONS

Allergic reactions and other idiosyncrasies are rarely 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.

8.2 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 5mg/kg of body weight.

10 OVERDOSAGE

Accidental ingestion of a usual treatment dose (3.7 ml or 1/8 fl. oz.) is not harmful. Treat with milk or antacids. 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 5mg 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 5mg fluoride/kg body weight (i.e., more than 2.3 mg fluoride/lb body weight) have been ingested, induce vomiting, give soluble calcium orally (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 body weight (i.e., more than 6.9 mg fluoride/lb body weight), induce vomiting and admit immediately to a hospital facility.