7-000-9377-00 0.25 mg Distr: Cypress Pharmaceuticals

Fluoride Chewable Tablets (Sodium Fluoride)

Rx Only

DESCRIPTION: Each Fluoride Chewable Tablet is sugar free, saccharin free and erythrosine (FD&C Red Dye #3) free. Each Fluoride 1 mg F^- tablet (full-strength) contains 1 mg fluoride ion (F^-) from 2.2 mg sodium fluoride (NaF). Each Fluoride 0.5 mg F^- tablet (half-strength) contains 0.5 mg F^- from 1.1 mg NaF. Each Fluoride 0.25 mg F^- tablet (quarter-strength) contains 0.25 mg F^- from 0.55 mg NaF.

Active Ingredient: Sodium Fluoride (NaF).

Inactive Ingredients: Xylitol, microcrystalline cellulose, malic acid, magnesium stearate, talc, citric acid, natural orange flavor, and sucralose.

CLINICAL PHARMACOLOGY: Sodium fluoride acts systemically (before tooth eruption) and topically (post-eruption) by increasing tooth resistance to acid dissolution, by promoting remineralization, and by inhibiting the cariogenic microbial process.

INDICATIONS AND USAGE: For once daily self-applied systemic use as a dental caries preventative. It has been established that ingestion of fluoridated drinking water (1 ppm F^-) during the period of tooth development results in a significant decrease in the incidence of dental caries.[1] Fluoride Chewable Tablets were developed to provide systemic fluoride for use as a supplement in patients from age 3 years to age 16 years living in areas where the drinking water fluoride content does not exceed 0.6 ppm F^-.

CONTRAINDICATIONS: Fluoride 1 mg F^- Tablets are contraindicated when the fluoride content of drinking water is 0.3 ppm F^- or more and should not be administered to pediatric patients under age 6 years. Fluoride 0.5 mg F^- Tablets are contraindicated when the fluoride content of drinking water is more than 0.6 ppm F^- and should not be administered to pediatric patients under age 6 when the fluoride content of drinking water is 0.3 ppm F^- or more or to pediatric patients under age 3 years. Fluoride 0.25 mg F^- Tablets are contraindicated when the fluoride content of drinking water is more than 0.6 ppm F^- and should not be administered to pediatric patients under age 3 years when the fluoride content of drinking water is 0.3 ppm F^- or more. Do not administer Fluoride Chewable Tablets (any strength) to pediatric patients under age 3 years due to choking hazard.

WARNINGS: Prolonged daily ingestion of quantities greater than the recommended amount may result in various degrees of dental fluorosis in pediatric patients under age 6 years, especially if the water fluoridation exceeds 0.6 ppm. Read directions carefully before using. Keep out of reach of infants and children.

PRECAUTIONS: General: Please refer to the **CONTRAINDICATIONS, WARNINGS** and **OVERDOSAGE** sections for overdosage concerns. Use in pediatric patients below the age of 3 years not recommended by current American Dental Association and American Academy of Pediatrics guidelines.

Drug Interactions: Do not eat or drink dairy products within one hour of fluoride administration. Incompatibility of fluoride with dairy foods has been reported due to formation of calcium fluoride which is poorly absorbed.

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 for 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. This dose is at least 400 times greater than the recommended daily dose of Fluoride Chewable Tablets. 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 is 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 doses of fluoride (5 mg/kg of body weight) did not result in impaired fertility and reproductive capabilities. This dose is approximately 200 times greater than the recommended daily dose of Fluoride Chewable Tablets.

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. 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 human milk and caution should be exercised when Fluoride Chewable Tablets 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. This dose is at least 200 times greater than the recommended daily dose of Fluoride Chewable Tablets.

Pediatric Use: The use of Fluoride Chewable Tablets as a caries preventive in pediatric age groups 3 to 16 years of age is supported by evidence from adequate and well controlled studies on fluoride supplementation from birth through adolescence.[1-5]

Geriatric Use: Fluoride Chewable Tablets (any strength) are not indicated for use in geriatric patients.

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

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 of Fluoride Chewable Tablets contains 0.25, 0.5 or 1 mg fluoride. The treatment of choice depends upon the age of the child and the water fluoride content. A bottle of 120 0.25 mg tablets contains 30 mg fluoride. A bottle of 120 0.5 mg tablets contains 60 mg fluoride. A bottle of 120 1 mg tablets contains 120 mg fluoride. [The total amount of sodium fluoride in a bottle of 120 Fluoride Chewable Tablets (all strengths) conforms with the recommendations of the American Dental Association for the maximum to be dispensed at one time for safety purposes.]

DOSAGE[2] AND ADMINISTRATION: Dissolve in the mouth or chew before swallowing, preferably at bedtime after brushing teeth. See schedule below to determine dosage.

Ages	Water F^- Content			
	0 ppm F^- to <0.3 ppm F^-	0.3 ppm F^- to 0.6 ppm F^-	>0.6 ppm F^-
3 to 6 yrs.	0.5 mg*	0.25 mg*	0
>6 to 16 yrs.	1 mg*	0.5 mg*	0

* per day

HOW SUPPLIED: Fluoride 1 mg F^- Chewable Tablets are available in bottles of 120 (NDC 60258-157-20) as off-white, orange flavored, round shaped chewable tablets. Debossed "SCI" on one side and "4" on the other.

Fluoride 0.5 mg F^- Chewable Tablets are available in bottles of 120 (NDC 60258-156-20) and bottles of 1000 (NDC 60258-156-10) as off-white, orange flavored, round shaped chewable tablets Debossed "SCI" on one side and "1007" on the other.

Fluoride 0.25 mg F^- Chewable Tablets are available in bottles of 120 (NDC 60258-155-20) as off-white, orange flavored, round shaped chewable tablets. Debossed "SCI" on one side and "6" on the other.

STORAGE: Store in a cool, dry place at a controlled room temperature 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) and away from heat and sunlight. Store in original container. Dispense in a tight, light-resistant container with a child-resistant closure as defined in the USP/NF.

Manufactured for Cypress Pharmaceutical, Inc., Madison, MS 39110

Manufactured by:
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I 376S Rev. 02/11

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