FLUORIDE- sodium fluoride tablet, chewable
PureTek Corporation

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.

Prescribing Information

DESCRIPTION

Each **Fluoride Chewable Tablet 1.0 mg** is erythrosine (FD&C Red Dye No. 3) free. Each tablet contains 1.0 mg F* from 2.2 mg sodium fluoride (NaF). Each tablet for oral administration contains sodium fluoride equivalent to fluoride 1.0 mg and the following inactive ingredients: croscarmellose sodium, FD&C Yellow No. 6 aluminum lake, magnesium stearate, mannitol, microcrystalline cellulose, orange flavor, sucrose.

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 preventive in pediatric patients. 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. Fluoride Chewable Tablets were developed to provide systemic fluoride for use as a supplement in pediatric patients from 6 months to 3 years of age and older living in areas where the drinking water fluoride content does not exceed 0.6 ppm F*.

CONTRAINDICATIONS

Fluoride Chewable Tablets 1.0 mg 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 the age of 6 years. Do not administer Fluoride Chewable Tablets (any strength) to pediatric patients under age 6 months.

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 the reach of children.

PRECAUTIONS

General: Please refer to CONTRAINDICATIONS, WARNINGS, OVERDOSAGE sections for overdosage concerns. Use in pediatric patients below the age of 6 months is 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 mg and 4.1 mg 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 in 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 ion is excreted in human milk. However, many drugs are excreted in human milk and caution should be exercised when **Fluoride Chewable Tablets 1.0 mg** are administered to nursing women. 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 1.0 mg** as a caries preventive in pediatric age groups 6 months to 16 years is supported by evidence from adequate and well-controlled studies on fluoride supplementation from birth through adolescence.

Geriatric Use

Fluoride Chewable Tablets 1.0 mg are not indicated for use in geriatric patients.

ADVERSE REACTIONS

Allergic rash and other idiosyncrasies have rarely been reported.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1 (800) FDA-1088.

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) has 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) has 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.

DOSAGE AND ADMINISTRATION

Dissolve in the mouth or chew before swallowing, preferably at bedtime after brushing teeth.

HOW SUPPLIED

Chewable tablets containing 1.0 mg fluoride are light peach-colored, orange flavor, un-scored, round, debossed “106”. Available in bottles of 120. NDC: 59088-106-73

STORAGE

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

***F** from sodium fluoride.

Inactive ingredients

croscarmellose sodium, FD&C Yellow No. 6 aluminum lake, magnesium stearate, mannitol, microcrystalline cellulose, orange flavor, sucrose.

Active Ingredient: **Per Tablet**
Fluoride 1.0 mg

Inactive Ingredients: croscarmellose sodium, FD&C Yellow No. 6 aluminum lake, magnesium stearate, mannitol, microcrystalline cellulose, orange flavor, sucrose.

DOSAGE AND ADMINISTRATION:
Dissolve in the mouth or chew before swallowing, preferably at bedtime after brushing teeth.

STORAGE: Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

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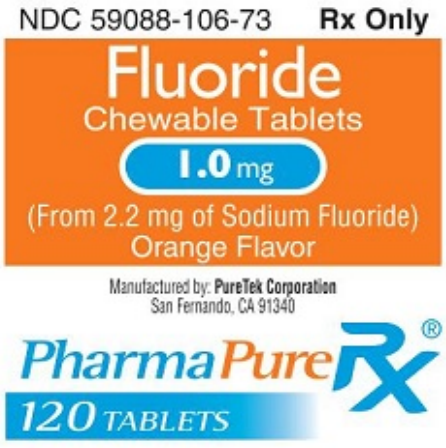

FLUORIDE

sodium fluoride tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-106
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	orange (light peach-colored)	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor	ORANGE (Orange flavored)	**Imprint Code**	106
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-106-73	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2011	

Labeler - PureTek Corporation (785961046)

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