FLOTREX- multivitamins, sodium fluoride 0.5 mg 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.

Flotrex (0.5 mg Fluoride)

Prescribing Information

DESCRIPTION:

Active Ingredients:

Each Chewable Tablet Contains:
Vitamin A (as Retinyl Acetate).....750 mcg RAE
Vitamin C (as Sodium Ascorbate 36 mg / Ascorbic Acid 24 mg)... 60 mg
Vitamin D3 (as Cholecalciferol)..... 10 mcg (400IU)
Vitamin E (as DL-Alpha Tocopheryl Acetate).....6.75 mg
Thiamin (as Thiamine Mononitrate)..... 1.05 mg
Riboflavin (as Vitamin B2).....1.2 mg
Niacin (as Niacinamide).....13.5 mg
Vitamin B6 (as Pyridoxine Hydrochloride)..... 1.05 mg
Folate (as Folic Acid)..... 510 mcg DFE (300 mcg Folic Acid)
Vitamin B12 (as Cyanocobalamin)..... 4.5 mcg
Fluoride (as Sodium Fluoride)..... 0.5 mg

Flotrex™ Chewable Multivitamin Tablets with 0.5 mg Fluoride

Active ingredient for caries prophylaxis: Fluoride as sodium fluoride.

Flotrex™ Chewable Multivitamin Tablets with 0.5 mg Fluoride provide fluoride and ten essential vitamins in a chewable tablet.

Other Ingredients: Aspartame, Croscarmellose Sodium, Flavor, Magnesium Stearate, Microcrystalline Cellulose, Stearic Acid (Vegetable), Sucrose, CI 42090 (FD&C Blue No. 1 Aluminum Lake), CI 45410 (Red 27 Lake).

Phenylketonurics: Contains Phenylalanine 3.0 mg Per Tablet.

CLINICAL PHARMACOLOGY

It is well established that fluoridation of the water supply (1 ppm fluoride) during the period of tooth development leads to a significant decrease in the incidence of dental caries.

Flotrex™ Chewable Multivitamin Tablets with 0.5 mg Fluoride provide sodium fluoride and ten essential vitamins in a chewable tablet. Because the tablets are chewable, they provide a topical as well as systemic source of fluoride. Hydroxyapatite is the principal crystal for all calcified tissue in the human body. The fluoride ion reacts with the hydroxyapatite in the tooth as it is formed to produce the more caries-resistant

crystal, fluorapatite. The reaction may be expressed by the equation:

$Ca_{10}(PO_4)_6(OH)_2 + 2F^- \text{------- } Ca_{10}(PO_4)_6F_2 + 2OH^-$

(Hydroxyapatite) (Fluorapatite)

Three stages of fluoride deposition in tooth enamel can be distinguished:

1. Small amounts (reflecting the low levels of fluoride in tissue fluids) are incorporated into the enamel crystals while they are being formed.

2. After enamel has been laid down, fluoride deposition continues in the surface enamel. Diffusion of fluoride from the surface inward is apparently restricted.

3. After eruption, the surface enamel acquires fluoride from the water, food, supplementary fluoride and smaller amounts from saliva.

INDICATIONS AND USAGE

This prescription chewable tablet is indicated for the prevention and treatment of vitamin and fluoride deficiencies in patients at high risk for dental caries and inadequate dietary intake of essential vitamins. It is specifically formulated to support normal growth and development, promote bone and dental health, and aid in the maintenance of overall metabolic and immune function.

Contraindications:

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

The American Academy of Pediatrics recommends that children up to the age 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation.

Flotrex™ Chewable Multivitamin Tablets with 0.5 mg Fluoride provide 0.50 mg fluoride in tablet form for children 6-16 years of age in areas where the drinking water fluoride level is less than 0.3 ppm.

Flotrex™ Chewable Multivitamin Tablets with 0.5 mg Fluoride supply significant amounts of Vitamins A, C, D, E, thiamine, riboflavin, niacin, vitamin B6, vitamin B12, and folate to supplement the diet, and to help assure that nutritional deficiencies of these vitamins will not develop. Thus, in a single easy-to-use preparation, children obtain ten essential vitamins and the important mineral, fluoride.

Children using **Flotrex™ Chewable Multivitamin Tablets with 0.5 mg Fluoride** regularly should receive semiannual dental examinations. The regular brushing of teeth and attention to good oral hygiene practices are also essential.

Flotrex™ Chewable Multivitamin Tablets with 0.5 mg Fluoride is a prescription product for the clinical dietary management of the metabolic processes of caries prophylaxis and provides supplementation of the diet with ten essential vitamins.

WARNING

Keep out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Caution: Do not eat or drink dairy products within one hour of fluoride administration.

Should be chewed. This product, as all chewable tablets, is not recommended for children under age 4 due to risk of choking.

PRECAUTION

The suggested dose of **Flotrex™ Chewable Multivitamin Tablets with 0.5 mg Fluoride** should not be exceeded, since dental fluorosis may result from continued ingestion of large amounts of fluoride. Before prescribing **Flotrex™ Chewable Multivitamin Tablets with 0.5 mg Fluoride:**

1. Determine the fluoride content of the drinking water from all major sources.

2. Make sure the child is not receiving significant amounts of fluoride from other sources such as medications and swallowed toothpaste.

3. Periodically check to make sure that the child does not develop significant dental fluorosis.

Folate in doses above 0.1 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive.There is a potential danger in administering folate to patients with undiagnosed anemia, since folate may obscure the diagnosis of pernicious anemia by alleviating the hematologic manifestations of the disease while allowing the neurologic complications to progress. This may result in severe nervous system damage before the correct diagnosis is made. Adequate doses of vitamin B12 may prevent, halt, or improve the neurologic changes caused by pernicious anemia. The patient’s medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

ADVERSE REACTIONS

Folate: Allergic sensitization has been reported following both oral and parenteral administration of folate. Adverse reactions have been reported with specific vitamins and minerals but generally at levels substantially higher than those contained herein. However, allergic and idiosyncratic reactions are possible at lower levels.

DOSAGE AND ADMINISTRATION

One tablet daily, to be dissolved in the mouth or chewed before swallowing. Do not give

a chewable tablet to a child younger than 4 years old.

HOW SUPPLIED

Flotrex™ Chewable Multivitamin Tablets with 0.5 mg Fluoride containing 0.5 mg fluoride are purple-colored, grape flavor, un-scored, tablets are available on prescription only in bottles of 30 tablets. NDC: 59088-015-54.

Dispense in a tight, light resistant container with a child–resistant closure as defined in the USP/NF. All prescription substitutions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

STORAGE

Do not use if bottle seal is broken.

Store at controlled room temperature 20° to 25°C (68° to 77°F).

[See USP Controlled Room Temperature].

Flotrex™ Chewable Multivitamin Tablets with 0.5 mg Fluoride

Manufactured in the USA by:

PureTek Corporation

Panorama City, CA 91402

Questions? Call toll-free: **1-877-921-7873**

FLOTREX

multivitamins, sodium fluoride 0.5 mg tablet, chewable

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-015
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.5 mg
VITAMIN A (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	750 ug
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	24 mg
SODIUM ASCORBATE (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	36 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	6.75 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.05 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.2 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	13.5 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	1.05 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	300 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ASPARTAME (UNII: Z0H242BBR1)	

Product Characteristics

Color	purple (Dark purple)	**Score**	no score
Shape	ROUND	**Size**	13mm
Flavor	GRAPE (Grape flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-015-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/21/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/21/2025	

Labeler - PureTek Corporation (785961046)

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