

Flotrex™

Chewable Multivitamin Tablets with 0.5 mg Fluoride

NDC: 59088-015-54



DERMACINRx

Description:

Flotrex™ is ideal for children and individuals needing fluoride supplementation. It supports daily nutritional needs for overall health and wellness while promoting healthy teeth and gums. Available in a chewable form for easy and convenient intake featuring a pleasant, kid-friendly taste for enhanced compliance.

Unit Detail:

30 tablets per bottle

Dosage:

One tablet daily or as directed under supervision of a licensed healthcare practitioner.

See reverse for complete prescribing information

Flotrex™ Chewable Multivitamin Tablets with 0.5 mg Fluoride

Active Ingredients:

Each Chewable Tablet Contains:

Vitamin A (as Retinyl Acetate)	750 mcg RAE
Vitamin C (as Ascorbic Acid: 24 mg, Sodium Ascorbate: 36 mg)	60 mg
Vitamin D3 (as Cholecalciferol)	10 mcg (400 IU)
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 HCl)	1.05 mg
Folate (as Folic Acid)(300 mcg Folic Acid)	510 mcg DFE
Vitamin B12 (as Cyanocobalamin)	4.5 mcg
Fluoride (as Sodium Fluoride).....	0.5 mg

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).

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.

Flotrex™ Chewable Multivitamin Tablets with 0.5 mg Fluoride provide 0.5 mg fluoride in tablet form for children 4-6 years of age in areas where the drinking water fluoride level is less than 0.3 ppm, and for children 6 years of age and above where the drinking water contains 0.3 through 0.6 ppm of fluoride.

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 and a mineral.

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.

WARNINGS AND PRECAUTIONS:

Keep this and all medications 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.

PRECAUTIONS

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.

Phenylketonurics: Contains Phenylalanine 3.0 mg Per Tablet.

ADVERSE REACTIONS

Allergic rash and other idiosyncrasies have been rarely reported.

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.

Do not use if bottle seal is broken.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

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

Use only under the direction of a licensed healthcare practitioner. If a patient experiences any side effects call your doctor. To report side effects, call **PureTek Corporation** at **1-877-921-7873**.

Manufactured by:

PureTek Corporation

Panorama City, CA 91402

For questions or information

call toll-free: **877-921-7873**