

**MULTIVITAMIN WITH FLUORIDE- .alpha.-tocopherol acetate, dl-, ascorbic acid, cyanocobalamin, folic acid, niacin, pyridoxine, riboflavin, sodium fluoride, thiamine mononitrate, vitamin a and vitamin d tablet, chewable
Method Pharmaceuticals, LLC**

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.

Multivitamin with Fluoride 0_25 mg

MULTIVITAMIN WITH FLUORIDE

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Prescribing Information

Each Fluoride Chewable Tablet Contains:

Supplement Facts

Dosage Size 1 Chewable Tablet

	Amount per Tablet	% DV Adults and Children 4 years or More
Vitamin A (as Vitamin A acetate)	2500 IU	50%
Vitamin C (as ascorbic acid)	60 mg	100%
Vitamin D (as cholecalciferol)	400 IU	100%
Vitamin E (dl-alpha tocopherol acetate)	15 IU	50%
Thiamine (as thiamine)	1.05 mg	70%
Riboflavin (as riboflavin)	1.2 mg	71%
Niacin (as niacinamide)	13.5 mg	68%
Vitamin B6 (as pyridoxine HCl)	1.05 mg	53%
Folate (as folic acid)	300 mcg	75%
Vitamin B12 (as cyanocobalamin)	4.5 mcg	75%
Fluoride (as sodium fluoride)	0.25 mg	*

*Daily value (DV) not established

Multivitamin with Fluoride 0.25 mg Chewable Tablets active ingredient for

caries prophylaxis: Fluoride as sodium fluoride

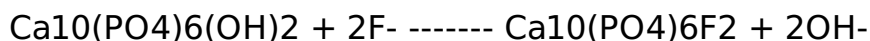
Multivitamin with Fluoride 0.25 mg Chewable Tablets provide sodium fluoride and ten essential vitamins in a chewable tablet.

Other ingredients: citric acid, magnesium stearate, mannitol, microcrystalline cellulose, orange flavor, sucralose, talc, xylitol.

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.

Multivitamin with Fluoride 0.25 mg Chewable Tablets 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:



(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

Supplementation of the diet with ten essential vitamins.

Supplementation of the diet with fluoride for caries prophylaxis.

Multivitamin with Fluoride 0.25 mg Chewable Tablets provide 0.25 mg fluoride in tablet form for children 4-6 years of age in areas where the drinking water contains 0.3 through 0.6 ppm of fluoride.

Multivitamin with Fluoride 0.25 mg Chewable Tablets 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. The American Academy of Pediatrics recommends that children up to age 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplements.

Children using **Multivitamin with Fluoride 0.25 mg Chewable Tablets** regularly should receive semiannual dental examinations. The regular brushing of teeth and attention to good oral hygiene practices are also essential. Multivitamin with Fluoride Chewable Tablets 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 **Multivitamin with Fluoride 0.25 mg Chewable Tablets** should not be exceeded, since dental fluorosis may result from continued ingestion of large amounts of fluoride.

Before prescribing **Multivitamin with Fluoride 0.25 mg Chewable Tablets**:

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.

ADVERSE REACTIONS

Allergic rash and other idiosyncrasies have been rarely reported.

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

Multivitamin Chewable tablets containing 0.25 mg fluoride are round yellowish/cream tablets with orange and yellow speckles. Debossed with "M163" on one side.

NDC: 58657-163-90 (90 count)

NDC: 58657-163-01 (100 count)

STORAGE

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature.

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.

Manufactured For:
Method Pharmaceuticals
Fort Worth, TX 76118

Rev. 06/2019

PRINCIPAL DISPLAY PANEL

NDC 58657-163-90
Multivitamin
with Fluoride
Chewable Tablets
0.25 mg
Orange Flavor
Rx Only
90 Tablets

Method Pharmaceuticals
NDC 58657-163-90

**Multivitamin
with Fluoride
Chewable Tablets**

0.25 mg
Orange Flavor
Rx Only
90 Tablets

Each Fluoride Chewable Tablet Contains:

Supplement Facts		
Dosage Size 1 Chewable Tablet		
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Vitamin A (as vitamin A acetate)	2500 IU / 1375 mcg	50%
Vitamin C (as ascorbic acid)	60 mg	100%
Vitamin D (as cholecalciferol)	400 IU / 10 mcg	100%
Vitamin E (as d-alpha tocopherol acetate)	15 IU / 10 mg	50%
Vitamin B ₁ (as thiamine)	1.05 mg	70%
Vitamin B ₂ (as riboflavin)	1.2 mg	71%
Niacin (as niacinamide)	13.5 mg	68%
Vitamin B ₆ (as pyridoxine HCl)	1.05 mg	53%
Vitamin B ₉ (as folic acid)	300 µg	75%
Vitamin B ₁₂ (as cyanocobalamin)	4.5 µg	75%
Fluoride (as sodium fluoride)	0.25 mg	*

* Daily value (DV) not established

Multivitamin with Fluoride 0.25 mg Chewable Tablets active ingredient for caries prophylaxis: Fluoride as sodium fluoride

Multivitamin with Fluoride 0.25 mg Chewable Tablets provide sodium fluoride and ten essential vitamins in a chewable tablet.

Other ingredients: citric acid, magnesium stearate, mannitol, microcrystalline cellulose, orange flavor, sucralose, talc, xylitol.

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PRINCIPAL DISPLAY PANEL

NDC 58657-163-01
Multivitamin
with Fluoride
Chewable Tablets
0.25 mg
Orange Flavor
Rx Only
100 Tablets



Each Fluoride Chewable Tablet Contains:

Supplement Facts		
Dosage Size 1 Chewable Tablet		
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MULTIVITAMIN WITH FLUORIDE

.alpha.-tocopherol acetate, dl-, ascorbic acid, cyanocobalamin, folic acid, niacin, pyridoxine, riboflavin, sodium fluoride, thiamine mononitrate, vitamin a and vitamin d tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:58657-163
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	2500 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
VITAMIN D (UNII: 9VU1KI44GP) (VITAMIN D - UNII:9VU1KI44GP)	VITAMIN D	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	15 [iU]
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.05 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.2 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	13.5 mg
PYRIDOXINE (UNII: KV2JZ1BI6Z) (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
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 mg

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

TALC (UNII: 7SEV7J4R1U)

XYLITOL (UNII: VCQ006KQ1E)

Product Characteristics

Color	yellow (yellowish/cream)	Score	no score
Shape	ROUND	Size	9mm
Flavor	ORANGE	Imprint Code	M163
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58657-163-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2018	
2	NDC:58657-163-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/20/2018	

Labeler - Method Pharmaceuticals, LLC (060216698)

Establishment

Name	Address	ID/FEI	Business Operations
Monarch PCM, LLC		080000294	manufacture(58657-163)

Revised: 2/2021

Method Pharmaceuticals, LLC