MULTI-VITAMIN WITH FLUORIDE- vitamin a, ascorbic acid, cholecalciferol, alpha-tocopherol acetate, thiamine hydrochloride, riboflavin 5-phosphate sodium, cyanocobalamin, niacinamide, pyridoxine hydrochloride and sodium fluoride liquid

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.

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Multi-Vitamin Drops with Fluoride 025 mg

### Multi-Vitamin Drops with Fluoride 0.25 mg

#### **Supplemental Facts**

	Percentage of U.S Allowance	. Recommended Daily
Each 1.0 mL supplies:		en 6 mos to 4 Years old
Vitamin A (as Vitamin A Palmitate)	1500 IU	60%
Vitamin C (as Ascorbic Acid)	35 mg	88%
Vitamin D (as Cholecalciferol)	400 IU	100%
Vitamin E (as D-Alpha-Tocopheryl Acid Succinate)	5 IU	50%
Vitamin B1 (as Thiamine HCI)	0.5 mg	71%
Vitamin B2 (as Riboflavin Phosphate Sodium)	0.6 mg	75%
Vitamin B12 (as Cyanocobalamin)	2 mcg	67%
Niacin (as Niacinamide)	8 mg	89%
Vitamin B6 (as Pyridoxine HCl)	0.4 mg	57%
Fluoride (as Sodium Fluoride)	0.25 mg	

<sup>\*</sup>Daily Value not established.

See INDICATIONS AND USAGE section for use by children 6 months to 6 years of age.

This product does not contain the essential vitamin folic acid.

**Active ingredient for caries prophylaxis:** Fluoride as sodium fluoride. This product does not contain Folic Acid.

**Other ingredients:** Cherry Flavor, Citric Acid Anhydrous, Glycerin, Orange Flavor, Potassium Sorbate, Propylene Glycol, Purified Water, Sodium Benzoate, Sorbitol Solution, Sucralose.

## **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

Hydroxyapatite is the principal crystal for all calcified tissue in the human body. The fluoride ion reacts with hydroxyapatite in the tooth as it is formed to produce the more caries-resistant crystal, fluorapatite.

The reaction may be expressed by the equation:

 $\begin{array}{c} \text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2 + 2\text{F-} & \text{Ca}_{10}(\text{PO}_4)_6\text{F}_2 + 20\text{H-} \\ & \text{(Hydroxyapatite)} & \text{(Fluorapatite)} \end{array}$ 

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

- Small amounts (reflecting the low levels of fluoride in tissue fluids) are incorporated into the enamel crystals while they are being formed.
- After enamel has been laid down, fluoride deposition continues in the surface enamel. Diffusion of fluoride from the surface inward is apparently restricted.
- After eruption, the surface enamel acquires fluoride from water, food, supplementary fluoride and smaller amounts from saliva.

## INDICATIONS AND USAGE

Supplementation of the diet with vitamins A, C and D.

Multi-Vitamin Drops with Fluoride 0.25 mg also provides fluoride for caries prophylaxis.

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 supplementation.

The American Academy of Pediatrics recommend that infants and young children 6 months to 3 years of age, in areas where the drinking water contains less than 0.3 ppm of fluoride, and children 3-6 years of age, in areas where the drinking water contains 0.3 through 0.6 ppm of fluoride, receive 0.25 mg of supplemental fluoride daily which is provided in a dose of 1 mL of Multi-Vitamin Drops with Fluoride 0.25 mg (See Dosage and Administration).

Multi-Vitamin Drops with Fluoride 0.25 mg supply significant

amounts of vitamins A, C and D 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 essential vitamins and fluoride.

## WARNINGS

As in the case of all medications, keep out of reach of children.

## **PRECAUTIONS**

The suggested dose should not be exceeded since dental fluorosis may result from continued ingestion of large amounts of fluoride.

When prescribing vitamin fluoride products:

- 1. Determine the fluoride content of the drinking water.
- 2. Make sure the child is not receiving significant amounts of fluoride from other medications and swallowed toothpaste.
- 3. Periodically check to make sure that the child does not develop significant dental fluorosis.

Multi-Vitamin Drops with Fluoride 0.25 mg should be dispensed in the original plastic container, since contact with glass leads to instability and precipitation. (The amount of

sodium fluoride in the 50 mL size is well below the maximum to be dispensed at one time according to recommendations of the American Dental Association.)

Important Considerations When Using Dosage Schedule:

- If fluoride level is unknown, drinking water should be tested for fluoride content before supplements are prescribed. For testing of fluoride content, contact the local or state health department.
- · All sources of fluoride should be evaluated with a thorough fluoride history. Patient exposure to multiple water sources can make proper prescribing complex.
- · Ingestion of higher than recommended levels of fluoride by children has been associated with an increase in mild dental fluorosis in developing, unerupted teeth.

Fluoride supplements require long-term compliance on a daily basis.

#### ADVERSE REACTIONS

Allergic rash and other idiosyncrasies have been rarely reported.

#### DOSAGE AND ADMINISTRATION:

See following chart. May be dropped directly into the mouth with dropper; or mixed with cereal, fruit juice or other food.

Fluoride Ion Level in Drinking Water (ppm)*				
Age	<0.3 ppm	0.3 - 0.6 ppm	>0.6 ppm	
Birth - 6 months	None	None	None	
6 mos - 3 years	0.25 mg (1 mL) / day †	None	None	
3 - 6 years	0.50 mg (2 mL) / day	0.25 mg (1 mL) / day	None	

<sup>\* 1.0</sup> ppm = 1 mg/liter

## **HOW SUPPLIED**

Multi-Vitamin and Fluoride 0.25 mg drops is available in 50 mL bottles with accompanying calibrated dropper.



## RECOMMENDED STORAGE

Store at controlled room temperature 15°-25°C (between 59°F and 77°F). Excursions Permitted. After opening store away from direct light. Close tightly after each use. Occasional deepening of color has no significant effect on vitamin potency

REFRIGERATION IS NOT REQUIRED.

SHAKE WELL.

# REFERENCES

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Mechanism of action, in Nizel AE (ed):

The Science of Nutrition and its Application in Clinical Dentistry. Philadelphia, WB Saunders Co, 1966, pp 331-347.

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Accepted Dental Therapeutics, ed 38, Chicago, 1979, p321.
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The clinical anticariogenic effectiveness of supplementary fluoridevitamin preparations - Results at the end of three years. *J Dent Children* 1966; 33 January: 3-12.

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Distributed by: Method Pharmaceuticals, LLC Fort Worth, TX 76118

877-250-3427 Rev. 01/17 Made in the USA

## PRINCIPAL DISPLAY PANEL

NDC 58657-325-50

Multi- Vitamin

Drops

With Fluoride

0.25 ma

1.69 FL. OZ. (50 mL)

<sup>&</sup>lt;sup>†</sup> 2.2 mg sodium fluoride contains 1 mg fluoride ion.



# **MULTI-VITAMIN WITH FLUORIDE**

vitamin a, ascorbic acid, cholecalciferol, alpha-tocopherol acetate, thiamine hydrochloride, riboflavin 5-phosphate sodium, cyanocobalamin, niacinamide, pyridoxine hydrochloride and sodium fluoride liquid

<b>Product Information</b>	Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:58657-325	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1500 [iU] in 1 mL		
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	35 mg in 1 mL		
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU] in 1 mL		
.ALPHATOCOPHEROL SUCCINATE, D- (UNII: LU4B53JYVE) (.ALPHATOCOPHEROL, D UNII:N9PR3490H9)	.ALPHATOCOPHEROL SUCCINATE, D-	5 [iU] in 1 mL		
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII: 4ABT0J945J)	THIAMINE	0.5 mg in 1 mL		
RIBOFLAVIN 5'-PHOSPHATE SODIUM (UNII: 20RD1DZH99) (FLAVIN MONONUCLEOTIDE - UNII:7N464URE7E)	FLAVIN MONONUCLEOTIDE	0.6 mg in 1 mL		
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII: P6YC3EG204)	CYANOCOBALAMIN	2 ug in 1 mL		
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	8 mg in 1 mL		
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII: KV2JZ 1BI6Z)	PYRIDOXINE HYDROCHLORIDE	0.4 mg in 1 mL		
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.25 mg in 1 mL		

Inactive Ingredients				
Ingredient Name	Strength			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
GLYCERIN (UNII: PDC6A3C0OX)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY, ORANGE	Imprint Code		
Contains				

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:58657- 325-50	1 in 1 BOX	02/24/2017			
1		50 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product				
N	Marketing Information					

Marketing Application Number or Monograph Marketing Start Marketing End

П	Category	Citation	Date	Date
	unapproved drug other		02/24/2017	

Labeler - Method Pharmaceuticals, LLC (060216698)

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Method Pharmaceuticals, LLC