



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

\* 1.0 ppm = 1 mg/liter

† 2.2 mg sodium fluoride contains 1 mg fluoride ion.

**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**

1. Brudevold F, McCann HG: Fluoride and caries control - 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.
2. American Academy of Pediatrics Committee on Nutrition: Fluoride supplementation, *Pediatrics* 1986; 77:758.
3. American Dental Association Council on Dental Therapeutics: *Accepted Dental Therapeutics*, ed 38, Chicago, 1979, p321.
4. Hennon DK, Stookey GK, Muhler JC: The clinical anticariogenic effectiveness of supplementary fluoride-vitamin preparations - Results at the end of three years. *J Dent Children* 1966; 33 January: 3-12.
5. Hennon DK, Stookey GK, Muhler JC: The clinical anticariogenic effectiveness of supplementary fluoride-vitamin preparations - Results at the end of four years. *J Dent Children* 1967; 34 November; 439- 443.
6. Hennon DK, Stookey GK, Muhler JC: The clinical anticariogenic effectiveness of supplementary fluoride-vitamin preparations - Results at the end of five and a half years. *Phar and Ther in Dent* 1970; 1:1.
7. Hennon DK, Stookey GK, Beiswanger BB: Fluoride-vitamin supplements: Effects on dental caries and fluorosis when used in areas with suboptimum fluoride in the water supply. *J Am Dent Assoc* 1977; 95-965

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

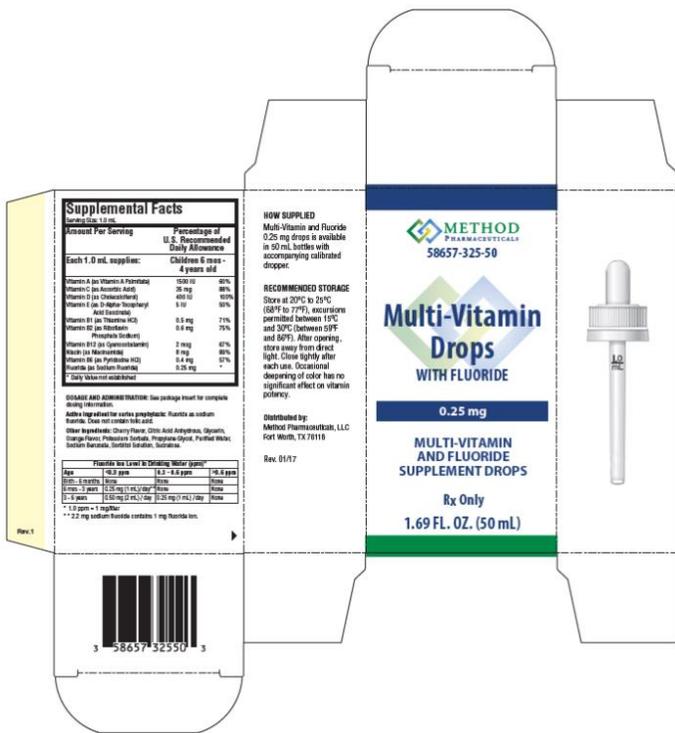
Multi- Vitamin

Drops

With Fluoride

0.25 mg

1.69 FL. OZ. (50 mL)



## 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

### Product Information

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) (VITAMIN A - UNII:81G40H8BOT)	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
.ALPHA.-TOCOPHEROL SUCCINATE, D- (UNII: LU4B53YVE) (.ALPHA.-TOCOPHEROL D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL SUCCINATE, D-	5 [IU] in 1 mL
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0945J)	THIAMINE	0.5 mg in 1 mL
RIBOFLAVIN 5'-PHOSPHATE SODIUM (UNII: 20RD1DZ H99) (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: 25X518RD4) (NIACINAMIDE - UNII:25X518RD4)	NIACINAMIDE	8 mg in 1 mL
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KVZJZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	0.4 mg in 1 mL
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3P5L)	
GLYCERIN (UNII: PDC6A3COOX)	
POTASSIUM SORBATE (UNII: 1VPU26JZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY, ORANGE	<b>Imprint Code</b>	
<b>Contains</b>			

### 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		

### Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

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

**Labeler** - Method Pharmaceuticals, LLC (060216698)

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Method Pharmaceuticals, LLC