MULTI-VITAMIN DROPS WITH FLUORIDE AND IRON- vitamin a, ascorbic acid, cholecalciferol, alpha-tocopherol acetate, thiamine hydrochloride, riboflavin 5-phosphate sodium, niacinamide, pyridoxine hydrochloride, ferrous sulfate 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.

Multi-Vitamin Drops with Fluoride and Iron 0_25 mg

Multi-Vitamin Drops with Fluoride and Iron 0.25 mg

Supplemental Facts

	Percentage of U.S. Recommended Daily Allowance	
Each 1.0 mL supplies:		**Children 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 HCl)	0.5 mg	71%
Vitamin B2 (as Riboflavin Phosphate Sodium)	0.6 mg	75%
Niacin (as Niacinamide)	8 mg	89%
Vitamin B6 (as Pyridoxine HCl)	0.4 mg	57%
Iron (as Ferrous Sulfate)	10 mg	100%
Fluoride (as Sodium Fluoride)	0.25 mg	*

*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:

$$\underset{\text{(Hydroxyapatite)}}{Ca_{10}(PO_4)_6(OH)_2} + 2F^- \rightarrow \underset{\text{(Fluorapatite)}}{Ca_{10}(PO_4)_6F_2} + 20H^-$$

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 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 and Iron 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 and Iron 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 Iron 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

* 1.0 ppm = 1 mg/liter

† 2.2 mg sodium fluoride contains 1 mg fluoride ion.

HOW SUPPLIED

Multi-Vitamin and Fluoride and
Iron 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. Brudevoid 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*
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

1986; 77:758.

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

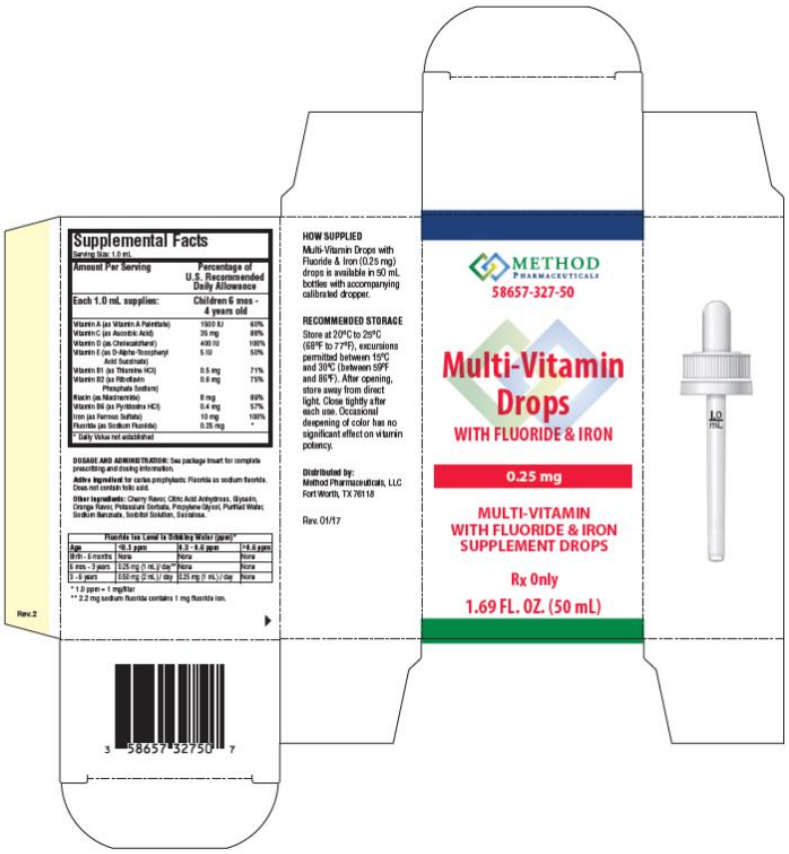
877-250-3427

Rev. 01/17

Made in the USA

PRINCIPAL DISPLAY PANEL

NDC 58657-327-50
Multi- Vitamin
Drops
With Fluoride & Iron
0.25 mg
1.69 FL. OZ. (50 mL)
Rx Only



MULTI-VITAMIN DROPS WITH FLUORIDE AND IRON

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

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:58657-327
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
.ALPHA.-TOCOPHEROL SUCCINATE, D- (UNII: LU4B53JYVE) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL 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
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	8 mg in 1 mL
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	0.4 mg in 1 mL
FERROUS SULFATE (UNII: 39R4TAN1VT) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	10 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: 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:58657-327-50	1 in 1 BOX	02/24/2017	
1		50 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/24/2017	

Labeler - Method Pharmaceuticals, LLC (060216698)

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