

**MULTI-VIT WITH FLUORIDE- vitamin a palmitate and ascorbic acid and cholecalciferol and .alpha.-tocopherol acetate, dl- and thiamine hydrochloride and riboflavin and niacinamide and pyridoxine hydrochloride and cyanocobalamin and sodium fluoride solution
Par Pharmaceutical**

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-VIT WITH FLUORIDE 0.5 mg DROPS

Rx only

Supplement Facts	
Dosage Size 1 mL (Mark on Dropper)	
Amount Per 1 mL	% Daily Value Children Under Age 4 Years
Vitamin A 1500 IU	60%
Vitamin C 35 mg	88%
Vitamin D 400 IU	100%
Vitamin E 5 IU	50%
Thiamin 0.5 mg	71%
Riboflavin 0.6 mg	75%
Niacin 8 mg	89%
Vitamin B ₆ 0.4 mg	57%
Vitamin B ₁₂ 2 mcg	67%
Fluoride 0.25 mg	*
*Daily Value (DV) not established	

Active ingredient for caries prophylaxis:

Each 1 mL contains 0.5 mg fluoride as sodium fluoride.

Other ingredients:

ascorbic acid (Vitamin C), caramel color, cholecalciferol (Vitamin D₃), cyanocobalamin (Vitamin B₁₂), dl-alpha-tocopheryl acetate (Vitamin E), ferrous sulfate, flavor, glycerin, niacinamide, polysorbate 80, purified water, pyridoxine hydrochloride (Vitamin B₆), riboflavin 5'-phosphate sodium (Vitamin B₂), sodium hydroxide, thiamine hydrochloride (Vitamin B₁), vitamin A palmitate.

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 the *hydroxyapatite* in the tooth as it is formed to produce the more caries-resistant crystal, *fluorapatite*. Three stages of fluoride deposition in tooth enamel can be distinguished:¹ 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 nine essential vitamins. Supplementation of the diet with 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.² MULTI-VIT with FLUORIDE 0.5 mg (multivitamin and fluoride supplement) drops provide fluoride in drop form for children ages 3 to 6 years in areas where the drinking water contains less than 0.3 ppm of fluoride and for children 6 years of age and older in areas where the drinking water contains 0.3 through 0.6 ppm of fluoride. Each 1 mL supplies sodium fluoride (0.5 mg fluoride) plus nine essential vitamins. MULTI-VIT with FLUORIDE 0.5 mg drops supply significant amounts of vitamins A, C, D, E, thiamin, riboflavin, niacin, vitamin B₆ and vitamin B₁₂ 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, infants and children obtain nine essential vitamins plus fluoride.

A comprehensive 5 1/2 year series of studies of the effectiveness of vitamin-fluoride products in caries protection has been published.^{3, 6} Children in this continuing study lived in an area where the water supply contained only 0.05 ppm fluoride. The subjects were divided into two groups, one which used only non-fluoridated vitamin products and other vitamin-fluoride products. The three-year interim report showed 63% fewer carious surfaces in primary teeth and 43% fewer carious surfaces in permanent teeth of the children taking vitamin-fluoride products.³

After four years the studies continued to support the effectiveness of vitamin-fluoride products, showing a reduction in carious surfaces of 68% in primary teeth and 46% in permanent teeth.⁴

Results at the end of 5 1/2 years further confirmed the previous findings and indicated that significant reductions in dental caries are apparent with the continued use of vitamin-fluoride products.⁵

WARNING:

As with all medicines, keep out of the 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 MULTI-VIT with FLUORIDE 0.5 mg drops: 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. MULTI-VIT with FLUORIDE 0.5 mg drops should be dispensed in the original plastic container, since contact with glass leads to instability and precipitation. (The amount of sodium fluoride in a 50-mL size is well below the maximum to be dispensed at one time according to recommendations of the American Dental Association.)

ADVERSE REACTIONS:

Allergic rash and other idiosyncrasies have been rarely reported.

DOSAGE AND ADMINISTRATION:

1 mL daily, or as prescribed. May be dropped directly into mouth with dropper, or mixed with fruit juice, cereal or other food.

USE FULL DOSAGE .

Occasional deepening of color has no significant effect on vitamin potency.

After opening, store away from direct light.

Your doctor or dentist is the best source of counsel and guidance in your child's fluoride supplementation .

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;331-347.
2. American Academy of Pediatrics, Committee on Nutrition: Fluoride Supplementation for Children: Interim Policy Recommendations. *Pediatrics*. 1995;95:777.
3. 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*. January 1966;33:3-12.
4. 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*. November 1967;34:439-443.
5. 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.
6. 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.

Manufactured for:

**QUALITEST PHARMACEUTICALS
130 VINTAGE DRIVE
HUNTSVILLE, AL 35811**

Rev. 3/15 R8
8268015

PRINCIPAL DISPLAY PANEL - carton

0.5 mg
FLUORIDE
WITH
MULTI-VIT
DROPS

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 the hydroxyapatite in the tooth as it is formed to produce the more caries-resistant crystal, 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 water, food, supplementary fluoride, and smaller amounts from saliva.

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A comprehensive 5 1/2 year series of studies of the effectiveness of vitamin-fluoride products in caries protection has been published.^{1,4} Children in this continuing study lived in an area where the water supply contained only 0.05 ppm fluoride. The subjects were divided into two groups, one which used only non-fluoridated vitamin products and other vitamin-fluoride products. The three-year interim report showed 63% fewer carious surfaces in primary teeth and 43% fewer carious surfaces in permanent teeth of the children taking vitamin-fluoride products.

After four years the studies continued to support the effectiveness of vitamin-fluoride products, showing a reduction in carious surfaces of 68% in primary teeth and 48% in permanent teeth.⁴

Results at the end of 5 1/2 years further confirmed the previous findings and indicated that significant reductions in dental caries are apparent with the continued use of vitamin-fluoride products.⁵

WARNING: As with all medicines, keep out of the 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 MULTI-VIT with FLUORIDE 0.5 mg drops: 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. MULTI-VIT with FLUORIDE 0.5 mg drops should be dispensed in the original plastic container, since contact with glass leads to instability and precipitation. (The amount of sodium fluoride in a 50-mL size is well below the maximum to be dispersed at

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ADVERSE REACTIONS: Allergic rash and other idiosyncrasies have been rarely reported.

DOSEAGE AND ADMINISTRATION: 1 mL daily, or as prescribed. May be dropped directly into mouth with dropper, or mixed with fruit juice, cereal or other food.

USE FULL DOSEAGE.

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NDC 0603-1450-47

MULTI-VIT
WITH
FLUORIDE
0.5 mg
DROPS

Multivitamin & Fluoride Supplement Drops

Rx only

50 mL
(1 2/3 FL OZ)

Qualitest®

DO NOT USE IF TAMPER-EVIDENT SEAL UNDER CAP IS BROKEN OR MISSING

Supplement Facts		
Dosage Size 1 mL (Mark on Dropper)		
Amount Per 1 mL	% Daily Value	Children Under Age 4 Years
Vitamin A 1500 IU	30%	
Vitamin C 35 mg	68%	
Vitamin D 400 IU	100%	
Vitamin E 5 IU	50%	
Niacin 8 mg	16%	
Riboflavin 0.6 mg	12%	
Thiamin 0.5 mg	10%	
Vitamin B ₆ 0.4 mg	8%	
Vitamin B ₁₂ 2 mcg	40%	
Fluoride 0.5 mg	-	
*Daily Value (DV) not established.		

Active ingredient for caries prophylaxis: Each 1 mL contains 0.5 mg fluoride as sodium fluoride.

Other ingredients: ascorbic acid (Vitamin C), caramel color, cholecalciferol (Vitamin D), cyanocobalamin (Vitamin B₁₂), dl-alpha-tocopheryl acetate (Vitamin E), ferrous sulfate, flavors, glycerin, niacinamide, polysorbate 80, purified water, pyridoxine hydrochloride (Vitamin B₆), riboflavin 5-phosphate sodium (Vitamin B₂), sodium hydroxide, thiamine hydrochloride (Vitamin B₁), vitamin A palmitate.

Manufactured for:
QUALITEST PHARMACEUTICALS
130 VINTAGE DRIVE
HUNTSVILLE, AL 35811

Rx 315 RB
0267990 1450



PRINCIPAL DISPLAY PANEL - label

NDC 0603-1450-47

MULTI-VIT WITH FLUORIDE

0.5 mg

DROPS

Multivitamin & Fluoride Supplement Drops

Rx only

50 mL (1 2/3 FL OZ)

Qualitest®

DO NOT USE IF TAMPER-EVIDENT SEAL UNDER CAP IS BROKEN OR MISSING

Supplement Facts

Dosage Size 1 mL (Mark on Dropper)

Amount Per 1 mL	% Daily Value Children Under Age 4 Years
Vitamin A 1500 IU	30%
Vitamin C 35 mg	68%
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Vitamin E 5 IU	50%
Thiamin 0.5 mg	10%
Riboflavin 0.6 mg	12%
Niacin 8 mg	16%
Vitamin B ₆ 0.4 mg	8%
Vitamin B ₁₂ 2 mcg	40%
Fluoride 0.5 mg	*

*Daily Value (DV) not established

Active ingredient for caries prophylaxis: Each 1 mL contains 0.5 mg fluoride as sodium fluoride. See box for dosage information and complete listing of ingredients. Save box for future use.

DISPENSE in original container.

WARNING: As with all medicines keep out of the reach of children. Your doctor or dentist is the best source of counsel and guidance in your child's fluoride supplementation.

Manufactured for:
QUALITEST PHARMACEUTICALS
130 VINTAGE DRIVE
HUNTSVILLE, AL 35811

Rx 415 RB
8067990 1450

non
varn

N 3 0603-1450-47 1

MULTI-VIT WITH FLUORIDE

vitamin a palmitate and ascorbic acid and cholecalciferol and .alpha.-tocopherol acetate, dl- and thiamine hydrochloride and riboflavin and niacinamide and pyridoxine hydrochloride and cyanocobalamin and sodium fluoride solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0603-1450
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 ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	5 [iU] in 1 mL
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (Thiamine ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	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:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	0.4 mg in 1 mL
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	2 ug in 1 mL
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
FERROUS SULFATE (UNII: 39R4TAN1VT)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0K00R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color	BROWN (clear and brown)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0603-1450-47	1 in 1 CARTON	06/19/1997	03/31/2021
1		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		06/19/1997	03/31/2021

Labeler - Par Pharmaceutical (011103059)

Revised: 11/2019

Par Pharmaceutical