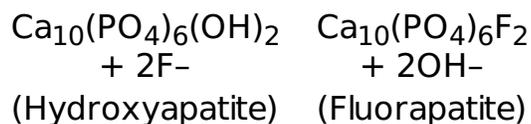


**MULTIVITAMIN WITH FLUORIDE DROPS- vitamin a palmitate, ascorbic acid, cholecalciferol, .alpha.-tocopherol, thiamine hydrochloride, riboflavin 5-phosphate sodium, niacinamide, pyridoxine hydrochloride, cyanocobalamin, and sodium fluoride solution/ drops
H2-Pharma, LLC**

MultiVitamin with Fluoride

CLINICAL PHARMACOLOGY

It is well established that fluoridation of the water supply (0.7 mg/L 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. The reaction may be expressed by the equation:



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 small amounts from saliva.

MultiVitamin with Fluoride Supplement Drops provide supplementation of the diet with nine essential vitamins, and with fluoride for caries prophylaxis. The American Academy of Pediatrics recommends that children up to the age 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation. MultiVitamin with Fluoride Supplement Drops provide fluoride in drop form for 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 for children ages 3 to 6 years in areas where the drinking water contains 0.3 through 0.6 ppm of fluoride.

Each 1.0 mL dose of MultiVitamin with Fluoride Supplement Drops 0.25 mg supplies sodium fluoride (0.25 mg fluoride) plus nine essential vitamins. MultiVitamin with Fluoride Supplement Drops 0.25 mg supply significant amounts of vitamins A, C, D, E, thiamine, riboflavin, niacinamide, pyridoxine and cyanocobalamin to supplement the diet, and to help ensure that nutritional deficiencies of these vitamins will not develop. Thus, in a single easy-to-use preparation, infants and children obtain nine essential vitamins and fluoride.

WARNINGS

As in the case of all medications, 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 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.

ADVERSE REACTIONS

Allergic rash or other idiosyncrasies have been rarely reported. To report SUSPECTED ADVERSE REACTIONS, contact H2-Pharma at 1-866-592-6438 or FDA at 1-800-FDA-1088 or via the web at www.fda.gov/medwatch for voluntary reporting of adverse reactions.

DOSAGE AND ADMINISTRATION

As directed by a physician. See American Dental Association (ADA) recommended supplement schedule below. May be dropped directly into the mouth with the enclosed dropper or mixed with cereal, fruit juice, or other food.

ADA Dietary Fluoride Supplement Schedule for Children at High Caries Risk

Age	Fluoride ion level in drinking water (ppm)*		
	<0.3 ppm	0.3-0.6 ppm	>0.6 ppm
Birth - 6 months	None	None	None
6 months - 3 years	0.25 mg/day†	None	None
3-6 years	0.50 mg/day	0.25 mg/day	None
6-16 years	1.0 mg/day	0.50 mg/day	None

* 1.0 part per million (ppm) = 1 milligram/liter (mg/L)

† 2.2 mg sodium fluoride contains 1 mg fluoride ion.

SHAKE WELL BEFORE USE.

HOW SUPPLIED

MultiVitamin with Fluoride Supplement Drops 0.25 mg are available in 50 mL bottles with accompanying calibrated dropper.

Dispense in original container.

RECOMMENDED STORAGE

Store at controlled room temperature, 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. After opening, store away from direct light. Close tightly after each use. REFRIGERATION IS NOT REQUIRED.

TAMPER EVIDENT: Do not use if seal under cap is torn, broken or missing.

Supplement Facts		
Serving Size 1.0 mL		
Servings Per Container 50		
	Amount Per Serving	% Daily Value
		Children over 4 & Adults
Vitamin A	450 mcg	50%
Vitamin C	35 mg	39%
Vitamin D	10 mcg (400 IU)	50%
Vitamin E	3.35 mg	22%
Thiamine	0.5 mg	42%
Riboflavin	0.6 mg	46%
Niacin	8 mg	50%
Vitamin B ₆	0.4 mg	24%
Vitamin B ₁₂	2 mcg	83%
Fluoride	0.25 mg	*

* Daily Value not established

*U.S. Recommended Daily Allowance not established.

Consult your physician for use by infants and young children 6 months to 3 years of age.

Active ingredient for caries prophylaxis: Fluoride as sodium fluoride.

Other ingredients: Ascorbic acid, caramel color, cherry flavor, cholecalciferol, citric acid, cyanocobalamin, d-alpha-tocopheryl acetate, ferrous sulfate, glycerin, methyl paraben, niacinamide, polysorbate 80, purified water, pyridoxine HCL, riboflavin-5-phosphate sodium, sodium benzoate, sodium fluoride, sodium hydroxide, sucralose, thiamine HCL, vitamin A palmitate.

Distributed by: **H2-Pharma, LLC**
Montgomery, AL 36117

www.h2-pharma.com

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Carton

61269-161-50

Drops

MultiVitamin
with Fluoride

Supplement Drops

1²/₃ fl. oz. (50 mL)

0.25 mg

H² pharma

61269-161-50



Drops

MultiVitamin with Fluoride

Supplement Drops

1²/₃ fl. oz. (50 mL)

0.25 mg



Supplement Facts

Serving Size 1.0 mL
Servings Per Container 50

	Amount Per Serving	% Daily Value Children over 4 & Adults
Vitamin A	450 mcg	50%
Vitamin C	35 mg	39%
Vitamin D	10 mcg (400 IU)	50%
Vitamin E	3.35 mg	22%
Thiamin	0.5 mg	42%
Riboflavin	0.6 mg	46%
Niacin	8 mg	50%
Vitamin B ₆	0.4 mg	24%
Vitamin B ₁₂	2 mcg	83%
Fluoride	0.25 mg	*

*Daily Value not established

*U.S. Recommended Daily Allowance not established.

Consult your physician for use by infants and young children 6 months to 3 years of age.

Active ingredient for caries prophylaxis:

Fluoride as sodium fluoride.

Other ingredients: Ascorbic acid, caramel color, cherry flavor, cholecalciferol, citric acid, cyanocobalamin, d-alpha-tocopheryl acetate, ferrous sulfate, glycerin, methyl paraben, niacinamide, polysorbate 80, purified water, pyridoxine HCL, riboflavin-5-phosphate sodium, sodium benzoate, sodium fluoride, sodium hydroxide, sucralose, thiamine HCL, vitamin A palmitate.

Distributed by: **H2-Pharma, LLC**
Montgomery, AL 36117
www.h2-pharma.com

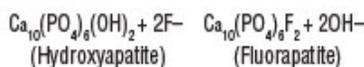




**Multivitamin
with Fluoride
Supplement Drops**
0.25 mg
1 2/3 fl. oz. (50 mL)

CLINICAL PHARMACOLOGY

It is well established that fluoridation of the water supply (0.7 mg/L 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. The reaction may be expressed by the equation:



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 small amounts from saliva.

Multivitamin with Fluoride Supplement Drops provide supplementation of the diet with nine essential vitamins, and with fluoride for caries prophylaxis. The American Academy of Pediatrics recommends that children up to the age 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation. Multivitamin with Fluoride Supplement Drops provide fluoride in drop form for 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 for children ages 3 to 6 years in areas where the drinking water contains 0.3 through 0.6 ppm of fluoride.

Each 1.0 mL dose of Multivitamin with Fluoride Supplement Drops 0.25 mg supplies sodium fluoride (0.25 mg fluoride) plus nine essential vitamins. Multivitamin with Fluoride Supplement Drops 0.25 mg supply significant amounts of vitamins A, C, D, E, thiamine, riboflavin, niacinamide, pyridoxine and cyanocobalamin to supplement the diet, and to help ensure that nutritional deficiencies of these vitamins will not develop. Thus, in a single

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.

ADVERSE REACTIONS Allergic rash or other idiosyncrasies have been rarely reported. To report SUSPECTED ADVERSE REACTIONS, contact H2-Pharma at 1-866-592-6438 or FDA at 1-800-FDA-1088 or via the web at www.fda.gov/medwatch for voluntary reporting of adverse reactions.

DOSAGE AND ADMINISTRATION: As directed by a physician. See American Dental Association (ADA) recommended supplement schedule below. May be dropped directly into the mouth with the enclosed dropper or mixed with cereal, fruit juice, or other food.

Age	Fluoride ion level in drinking water (ppm) *		
	<0.3 ppm	0.3-0.6 ppm	>0.6 ppm
Birth - 6 months	None	None	None
6 months - 3 years	0.25 mg/day**	None	None
3-6 years	0.50 mg/day	0.25 mg/day	None
6-16 years	1.0 mg/day	0.50 mg/day	None

* 1.0 part per million (ppm) = 1 milligram/liter (mg/L)
**2.2 mg sodium fluoride contains 1 mg fluoride ion.

SHAKE WELL BEFORE USE.

HOW SUPPLIED Multivitamin with Fluoride



ensure that nutritional deficiencies of these vitamins will not develop. Thus, in a single easy-to-use preparation, infants and children obtain nine essential vitamins and fluoride.

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

Supplement Drops 0.25 mg are available in 50 mL bottles with accompanying calibrated dropper.

Dispense in original container.

RECOMMENDED STORAGE Store at controlled room temperature, 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. After opening, store away from direct light. Close tightly after each use. REFRIGERATION IS NOT REQUIRED.

TAMPER EVIDENT: Do not use if seal under cap is torn, broken or missing.

1800111[02]

MULTIVITAMIN WITH FLUORIDE DROPS

vitamin a palmitate, ascorbic acid, cholecalciferol, .alpha.-tocopherol, thiamine hydrochloride, riboflavin 5-phosphate sodium, niacinamide, pyridoxine hydrochloride, cyanocobalamin, and sodium fluoride solution/ drops

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:61269-161
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) (VITAMIN A - UNII:81G40H8B0T, RETINOL - UNII:G2SH0XKK91)	VITAMIN A	450 ug 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	10 ug in 1 mL
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.- TOCOPHEROL	3.35 mg in 1 mL
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	0.5 mg in 1 mL
RIBOFLAVIN 5'-PHOSPHATE SODIUM DIHYDRATE (UNII: 20RD1DZH99) (RIBOFLAVIN 5'-PHOSPHATE - UNII:7N464URE7E)	RIBOFLAVIN 5'- PHOSPHATE	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
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	2 ug in 1 mL
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARAMEL (UNII: T9D99G2B1R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FERROUS SULFATE (UNII: 39R4TAN1VT)	
CHERRY (UNII: BUC5I9595W)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:61269-161-50	1 in 1 CARTON		
1		50 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		01/04/2017	

Supplement Facts

Serving Size : _____ **Serving per Container :** _____

Amount Per Serving	% Daily Value
color	
flavor	

Labeler - H2-Pharma, LLC (028473634)