

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

| Supplement Facts | | |
|----------------------------------|---------------------------|----------------------|
| Serving Size 1.0 mL | | |
| Servings Per Container 50 | | |
| | Amount Per Serving | % Daily Value |
| Vitamin A | 1500 IU | 60% |
| Vitamin C | 35 mg | 88% |
| Vitamin D | 400 IU | 100% |
| Vitamin E | 5 IU | 50% |
| Thiamine | 0.5 mg | 71% |
| Riboflavin | 0.6 mg | 75% |
| Niacinamide | 8 mg | 89% |
| Vitamin B ₆ | 0.4 mg | 57% |
| Vitamin B ₁₂ | 2 mcg | 67% |
| Fluoride | 0.5 mg | * |

* Daily Value not established

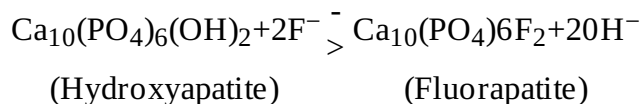
*U.S. Recommended Daily Allowance not established. Consult your physician for use by infants and children 2 years of age.

Active ingredient for caries prophylaxis: Fluoride as sodium fluoride.

Other ingredients: Ascorbic acid, caramel color, cholecalciferol, citric acid, cyanocobalamin, d-alpha-tocopheryl acid succinate, ferrous sulfate, flavor, 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.

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. 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 smaller amounts of saliva.

MultiVitamin with Fluoride Supplement Drops 0.5 mg provide supplementation of the diet with nine essential vitamins, as well as sodium 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 and Fluoride Supplemental Drops 0.5 mg** 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 3-6 years, in areas where the drinking water contains 0.3 through 0.6 ppm of fluoride. Each 1.0 mL supplies sodium fluoride (0.5 mg fluoride) plus nine essential vitamins. The American Academy of Pediatrics recommends that infants and young children 6 months to 3 years of age, in areas where 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 full dose (1 mL) of **MultiVitamin and Fluoride Supplemental Drops 0.5 mg**. A half dose (0.5 mL) of **MultiVitamin and Fluoride Supplemental Drops 0.5 mg** could also provide a daily fluoride intake of 0.25 mg; however, the dosage reduces vitamin supplementation by half.

MultiVitamin and Fluoride Supplemental Drops 0.5 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. A comprehensive 5 ½ year series of studies of the effectiveness of multivitamins and fluoride drops in caries protection has been published. 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 the non-fluoride vitamin drops, and the other group used multivitamin-fluoride drops. 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 multivitamin-fluoride products. After four years, the studies continued to support the effectiveness of multivitamin-fluoride products, showing a reduction in carious surfaces of 68% in primary teeth and 46% in permanent teeth. Results at the end of the 5 ½ years further confirmed the previous findings and indicated that significant reductions in dental caries are apparent with the continued use of multivitamin-fluoride products. These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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 recommending 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. 4. MultiVitamin and Fluoride Supplemental Drops 0.5 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 the recommendations of the American Dental Association.)

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

1.0 mL daily or as recommended by a physician. May be dropped directly into the mouth with the enclosed dropper or mixed with cereal, fruit juice, or other food.

HOW SUPPLIED

MultiVitamin and Fluoride Supplemental Drops 0.5 mg are available in 50 mL bottles with accompanying calibrated dropper.

RECOMMENDED STORAGE

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

TAMPER EVIDENT: Do not use if printed bottle seal around bottle cap is broken or missing.

Distributed by: **H2-Pharma, LLC**
2010 Berry Chase Place, Montgomery, AL 36117
www.h2-pharma.com

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Label

61269-162-50

MultiVitamin
with Fluoride

Supplement Drops

1 fl. oz. (50 mL)

0.5 mg

H² pharma



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

61269-162-50

MultiVitamin
with Fluoride

Supplement Drops

1²/₃ fl. oz. (50 mL)

0.5 mg



SHAKE WELL

DOSAGE: See carton for dosage and administration information.

USE FULL DOSAGE

*U.S. Recommended Daily Allowance has not been established.

Active ingredient for caries prophylaxis:

Each 1 mL contains 0.5 mg fluoride as sodium fluoride.

Other Ingredients: Ascorbic acid, caramel color, cholecalciferol, citric acid, cyanocobalamin, dl-alpha-tocopheryl acetate, ferrous sulfate, flavor, 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.

Tamper Evident: Do not use if seal under cap is torn, broken or missing.
WARNING: KEEP OUT OF REACH OF CHILDREN.

Supplement Facts

Serving Size 1.0 mL
Servings Per Container 50

| | Amount Per Serving | % Daily Value |
|-------------------------|--------------------|---------------|
| Vitamin A | 1500 IU | 60% |
| Vitamin C | 35 mg | 88% |
| Vitamin D | 400 IU | 100% |
| Vitamin E | 5 IU | 50% |
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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:61269-162 |
| 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 (UNII: H4N855PNZ1) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1) | .ALPHA.-TOCOPHEROL | 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: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 | 0.5 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) | |
| METHYL PARABEN (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:61269-162-50 | 1 in 1 CARTON | | |
| 1 | | 50 mL in 1 BOTTLE | | |

