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:

$$Ca_{10}(PO_4)_6(OH)_2 + 2F^- \rightarrow Ca_{10}(PO_4)_6F_2 + 2OH^-$$

(Hydroxyapatite) (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 small amounts from saliva.

MultiVitamin with Fluoride Supplemental Drops provide supplementation of the diet with sodium fluoride and nine essential vitamins. Supplementation of the diet 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 and Fluoride Supplemental Drops 0.25 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 (0.25 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 0.25 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 supplemention by half. MultiVitamin and Fluoride Supplemental Drops 0.25 mg and 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 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 and fluoride. A comprehensive 5-1/2 year series of studies of the effectiveness of multivitamin, iron, 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 2 groups, one which used only the non-fluoride vitamin product, and the other, multivitamins-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 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 5-1/2 years futher 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 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. 4. MultiVitamin and Fluoride Supplemental Drops 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.)

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 ADMINISTATION 1.0 mL daily or as directed 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 0.25 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 light. Close tightly after each use. REFRIGERATION IS NOT REQUIRED.

61269-161-50

Drops

MultiVitamin

with Fluoride

Rx

Supplement Drops

1 2/3 fl. oz. (50 mL)

0.25 mg

H² pharma

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	0.25 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: Each 1 mL contains 0.25 mg 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.

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