H²pharma

0.25 mg

MultiVitamin,
Iron and Fluoride Rx
Supplement Drops
1 2/3 fl. oz. (50 mL)

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 form 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, Iron and Fluoride Supplement Drops 0.25 mg provide supplementation of the diet with iron and eight 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, Iron and Fluoride Supplemental Drops 0.25 mg** provide fluoride in drop form for children 2 to 3 years of age, in areas where the drinking water contains less than 0.3 ppm of fluoride; and for children over 3 years, in areas where the drinking water contains 0.3 through 0.7 ppm of fluoride. Each 1.0 mL supplies sodium fluoride (0.25 mg fluoride) plus eight essential vitamins and iron. The American Academy of Pediatrics and the American Dental Association currently recommend that infants and young children under 2 years of age, in areas where the drinking water contains less then 0.3 ppm of fluoride, and children 2-3 years of age, in the areas where the drinking water contains 0.3 through 0.7 ppm of fluoride, receive 0.25 mg of supplemental fluoride daily which is provided in a full dose (1mL) of **MultiVitamin, Iron and Fluoride Supplemental Drops 0.25 mg**. **MultiVitamin, Iron and Fluoride Supplemental Drops 0.25 mg** provide significant amounts of vitamins A, C, D, E, thiamine, riboflavin, niacinamide, pyridoxine and iron to supplement the diet, and to help ensure that nutritional deficiencies of these vitamins will not develop.
*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, Iron 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 Infants and children under 2 years of age: 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, Iron 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 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.

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Drops

MultiVitamin, Iron and Fluoride

Rx

Supplement Drops

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

0.25 mg

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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%
Iron	10 mg	100%
Fluoride	0.25 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: Each 1 mL contains 0.25 mg fluoride as sodium fluoride.
Other ingredients: Ascorbic acid, caramel color, cholecalciferol, citric acid, d-alpha-tocopheryl acid succinate, ferrous sulfate, flavor, glycerin, methyl paraben, niacinamide, polysorbate 80, purified water, pryidoxine HCl, riboflavin-5-phosphate sodium, sodium benzoate, sodium fluoride, sodium hydroxide, sucralose, thiamine HCl, vitamin A palmitate.

Distributed by: **H2-Pharma, LLC**
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