TRI-VIT WITH FLUORIDE 0.25 mg 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] 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: TRI-VIT with FLUORIDE 0.25 mg drops may be useful for infants whose diets are lacking in vitamins A, D and C. TRI-VIT with FLUORIDE 0.25 mg drops also provide fluoride for caries prophylaxis. TRI-VIT with FLUORIDE 0.25 mg (vitamins A, D, C, and fluoride) drops were developed to provide fluoride in drop form for infants and young children from 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.[2,3] Each 1 mL supplies sodium fluoride (0.25 mg fluoride) plus three basic vitamins.

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 TRI-VIT with FLUORIDE 0.25 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.

TRI-VIT with FLUORIDE 0.25 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 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 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.**

DISPENSE in original container

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(5):777.
3. American Dental Association Council on Dental Therapeutics. New Fluoride Schedule Adopted. *ADA News*. May 16, 1994;12-14.

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.

NDC 0603-1785-47

TRI-VIT WITH FLUORIDE 0.25 mg DROPS

Vitamin A, D, C & Fluoride Supplement Drops

Rx only

50 mL (1 2/3 FL OZ)

N 3 0603-1785-474

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 Infants	% Daily Value Children Under Age 4 Years
Vitamin A 1500 IU	100%	60%
Vitamin C 35 mg	100%	88%
Vitamin D 400 IU	100%	100%
Fluoride 0.25 mg	*	*

*Daily Value (DV) not established

Active ingredient for caries prophylaxis:
Each 1 mL contains 0.25 mg fluoride as sodium fluoride.

Other ingredients: ascorbic acid (Vitamin C), caramel color, cholecalciferol (Vitamin D_3), flavor, glycerin, polysorbate 80, purified water, sodium hydroxide, vitamin A palmitate.

See box for dosage information and complete listing of ingredients. Save box for future use.

DISPENSE in original container

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

Rev. 6/08 R5
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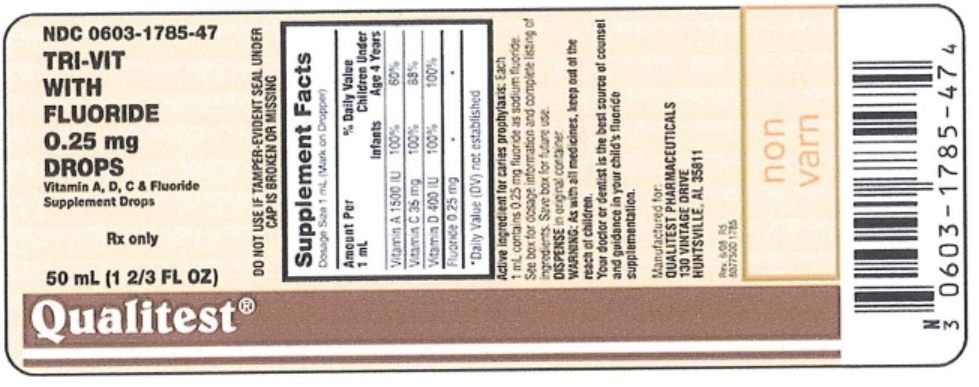
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA.