

TRI-VITE DROPS WITH FLUORIDE- ascorbic acid, sodium fluoride, vitamin a and vitamin d solution

Method Pharmaceuticals, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Tri-Vite Drops with Fluoroide 0_5 mg

Supplement Facts

Serving Size: 1.0 mL

Amount Per Serving		Percentage of U.S. Recommended Daily Allowance
Each 1.0 mL supplies:		Children 6 mos - 4 years old
Vitamin A	1500 IU	60%
Vitamin C	35 mg	88%
Vitamin D	400 IU	100%
Fluoride (as Sodium Fluoride)	0.5 mg	*

* Daily Value not established

See **INDICATIONS AND USAGE** section for use by children 6 months to 6 years of age. This product does not contain the essential vitamin folic acid.

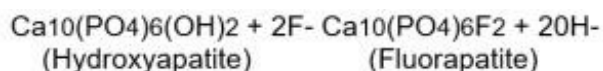
Active ingredient for caries prophylaxis: Fluoride as sodium fluoride. Does not contain folic acid.

Other ingredients: caramel color, cherry flavor, EDTA, glycerin, polysorbate 80, potassium sorbate, purified water, sodium benzoate, sorbitol solution, sucralose.

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 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 from saliva.

INDICATIONS AND USAGE

Supplementation of the diet with vitamins A, C and D. Tri-Vite Drops with Fluoride 0.5 mg also provides fluoride for caries prophylaxis.

The American Academy of Pediatrics recommend that 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 children 3-6 years of age, in areas where the drinking water contains 0.3 through 0.6 ppm of fluoride, receive 0.5 mg of supplemental fluoride daily which is provided in a dose of 1 mL of Tri-Vite Drops with Fluoride 0.5 mg (**See Dosage and Administration**).

Tri-Vite Drops with Fluoride 0.5 mg supply significant amounts of vitamins A, C and D 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, children obtain essential vitamins and fluoride.

WARNINGS

As in the case of all medications, keep out of 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.

Tri-Vite Drops with Fluoride 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 recommendations of the American Dental Association.)

Important Considerations When Using Dosage Schedule:

- If fluoride level is unknown, drinking water should be tested for fluoride content before supplements are prescribed. For testing of fluoride content, contact the local or state

health department.

- All sources of fluoride should be evaluated with a thorough fluoride history. Patient exposure to multiple water sources can make proper prescribing complex.
- Ingestion of higher than recommended levels of fluoride by children has been associated with an increase in mild dental fluorosis in developing, unerupted teeth.
- Fluoride supplements require long-term compliance on a daily basis.

ADVERSE REACTIONS

Allergic rash and other idiosyncrasies have been rarely reported.

DOSAGE AND ADMINISTRATION

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

Tri-Vite Drops with Fluoride 0.5 mg is available in 50 mL bottles with accompanying calibrated dropper.

RECOMMENDED STORAGE

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). After opening, store away from direct light. Close tightly after each use. Occasional deepening of color has no significant effect on vitamin potency.

REFRIGERATION IS NOT REQUIRED.

SHAKE WELL.

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, pp 331-347.
2. American Academy of Pediatrics Committee on Nutrition: Fluoride supplementation, *Pediatrics* 1986; 77:758.
3. American Dental Association Council on Dental Therapeutics: *Accepted Dental Therapeutics*, ed 38, Chicago, 1979, p321.
4. Hennon DK, Stookey GK, Muhler JC: The clinical anticariogenic effectiveness of supplementary fluoride-vitamin preparations - Results at the end of three years. *J Dent Children* 1966; 33 January: 3-12.
5. Hennon DK, Stookey GK, Muhler JC: The clinical anticariogenic effectiveness of supplementary fluoride-vitamin preparations - Results at the end of four years. *J Dent Children* 1967; 34 November; 439- 443.
6. Hennon DK, Stookey GK, Muhler JC: The clinical anticariogenic effectiveness of supplementary fluoride-vitamin preparations - Results at the end of five and a half years.

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7. Hennon DK, Stookey GK, Beiswanger BB: Fluoride-vitamin supplements: Effects on dental caries and fluorosis when used in areas with suboptimum fluoride in the water supply. *J Am Dent Assoc* 1977; 95-965

Distributed by:

Method Pharmaceuticals, LLC

Fort Worth, TX 76118

1-877-250-3427

Rev. 07/2018

PRINCIPAL DISPLAY PANEL

NDC 58657-324-50

Tri-Vite

Drops

WITH FLUROIDE

0.5 mg

1.69 FL. OZ. (50 mL)



TRI-VITE DROPS WITH FLUORIDE

ascorbic acid, sodium fluoride, vitamin a and vitamin d solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:58657-324
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A (UNII: 81G40H8B0T) (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
VITAMIN D (UNII: 9VU1KI44GP) (VITAMIN D - UNII:9VU1KI44GP)	VITAMIN D	400 [iU] in 1 mL
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EDETIC ACID (UNII: 9G34HU7RV0)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	brown (caramel color)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58657-324-50	1 in 1 CARTON	07/25/2018	
1		50 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/25/2018	

Labeler - Method Pharmaceuticals, LLC (060216698)