

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.

Multi-Vitamin and Fluoride 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.)

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

See following chart. May be dropped directly into mouth with dropper; or mixed with cereal, fruit juice or other food.

DOSAGE AND ADMINISTRATION -continued

Fluoride Ion Level in Drinking Water (ppm)*			
Age	<0.3 ppm	0.3-0.6 ppm	>0.6 ppm
Birth - 6 months	None	None	None
6 mos - 3 years	0.25 mg (1 mL) / day**	None	None
3 - 6 years	0.50 mg (2 mL) / day	0.25 mg (1 mL) / day	None

* 1.0 ppm = 1 mg/liter
** 2.2 mg sodium fluoride contains 1 mg fluoride ion.

HOW SUPPLIED

Multi-Vitamin and Fluoride 0.25 mg drops is available in 50 mL bottles with accompanying calibrated dropper.



RECOMMENDED STORAGE

Store at controlled room temperature, 15°-25°C (59°-77°F). Excursions permitted. 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 Niaz AE (ed): *The Science of Nutrition and its Application to Clinical Dentistry*. Philadelphia, WB Saunders Co, 1966, pp 331-347.
2. American Academy of Pediatrics Committee on Nutrition: Fluoride supplementation, *Pediatrics* 1988; 77:758.
3. American Dental Association Council on Dental Therapeutics: *Accepted Dental Therapeutics*, ed 38, Chicago, 1979, p 321.
4. Hannon DK, Stockoy GK, Muhler JC: The clinical anticariogenic effectiveness of supplementary fluoride-vitamin preparations - Results at the end of three years. *J Dent Children* 1968; 33 January: 3-12.
5. Hannon DK, Stockoy 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. Hannon DK, Stockoy GK, Muhler JC: The clinical anticariogenic effectiveness of supplementary fluoride-vitamin preparations - Results at the end of five and a half years. *Phar and Ther in Dent* 1970; 1:1.
7. Hannon DK, Stockoy GK, Selwinger 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.

Manufactured for: Boca Pharmacal, Inc., Coral Springs, FL 33065 www.bocapharmaceutical.com 1-800-354-8460 Rev. 05/11



NDC 64376-820-50
**Multi-Vitamin
Drops
With Fluoride**

0.25 mg

**MULTI-VITAMIN
AND FLUORIDE
SUPPLEMENT DROPS**

Rx Only

1.69 FL. OZ. (50 mL)

Supplement Facts

Serving Size: 1.0 mL

Amount Per Serving	Percentage of U.S. Recommended Daily Allowance	Children 6 mos - 4 years old
Each 1.0 mL suppl etc		
Vitamin A (as Vitamin A Palmitate)	1500 IU	60%
Vitamin C (as Ascorbic Acid)	35 mg	66%
Vitamin D (as Cholecalciferol)	400 IU	100%
Vitamin E (as D-Alpha-Tocopheryl Acid Succinate)	5 IU	50%
Vitamin B1 (as Thiamine HCl)	0.5 mg	71%
Vitamin B2 (as Riboflavin)	0.6 mg	75%
Vitamin B12 (as Cyanocobalamin)	2 mcg	67%
Niacin (as Nicotinamide)	8 mg	88%
Vitamin B6 (as Pyridoxine HCl)	0.4 mg	57%
Fluoride (as Sodium Fluoride)	0.25 mg	

*Daily Value not established

DOSAGE AND ADMINISTRATION: See package insert for complete dosing information.

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