

MULTI-VITAMIN FLUORIDE DROPS - vitamin a, vitamin c, vitamin d, vitamin e, vitamin b1, vitamin b2, vitamin b12, niacin, vitamin b6, flouride solution

H.J. Harkins Company, Inc.

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.

Unknown Title

MULTI-VITAMIN FLUORIDE DROPS

0.25 mg per mL

Rx Only

DESCRIPTION

Each 1.0 mL supplies: **Percentage of U.S. Recommended Daily Allowance**
Children 6 mos to 4 years old

Vitamin A (as Vitamin A palmitate)	1500 IU	60%
Vitamin C (as Ascorbic Acid)	35 mg	88%
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 Phosphate Sodium)	0.6 mg	75%
Vitamin B12 (as Cyanocobalamine)	2 mcg	67%
Niacin (as Niacinamide)	8 mg	89%
Vitamin B6 (as Pyridoxine HCl)	0.4 mg	57%
Fluoride (as Sodium Fluoride)	0.25 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.

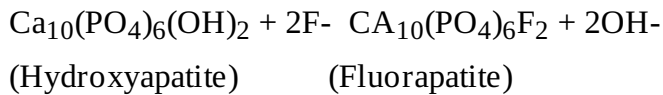
Other ingredients: Caramel color, cherry flavor, ferrous sulfate, oil of orange, glycerin, methylparaben, polysorbate 80, purified water, sodium benzoate and sodium hydroxide.

CLINICAL PHARMACOLOGY

It is well established that fluoridation of 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:¹



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.

Multi-Vitamin Fluoride Drops 0.25 mg also provide fluoride for caries prophylaxis.

The American Academy of Pediatrics recommends that children up to age 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation.

The American Academy of Pediatrics recommend 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 dose of 1 mL of Multi-Vitamin Fluoride 0.25 mg drops. (see Dosage and Administration).

Multi-Vitamin Fluoride 0.25 mg drops 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.

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.

Age	Fluoride Ion Level in Drinking Water (ppm)*		
	<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 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, p 321.
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. *Phar and Ther in Dent* 1970; 1:1.
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 DentAssoc* 1977; 95-965.

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

52959-593-50
RX Only: #XXXXXXXXX
#XXX

POLYVIT. w/FLUOR DROPS 0.25mg

Lot #: PV273HI
Mfg: HI-TECH
Exp: 10/11
Mfg Coral Springs,
Loc.: FL

Compare to: Poly-Vi-Flor
Mfg. NDC: 64376-820-50
Pill ID: Fluid

Take as directed by your Doctor or
See outsert for usual dosage information

CAUTION: Federal law PROHIBITS the transfer of this drug to anyone other than the person to whom prescribed and prohibits dispensing without a prescription unless OTC. See outsert for add'l RX info KEEP OUT OF REACH OF CHILDREN. Store in a cool dry place 68 to 77 degrees F.

POLYVIT. w/FLUOR DROPS 0.25mg		
52959-593-50	Qty	50ml
10/11	Lot	PV273HI
Poly-Vi-Flor		64376-820-50

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52959-593-50	Qty	50ml
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52959-593-50	Qty	50ml
10/11	Lot	PV273HI
Poly-Vi-Flor		64376-820-50

Repack: HJ Harkins Co., Inc. Nipomo, CA 93444
Dispense in tight, child & light-resistant container per USP

[Rev 7]

MULTI-VITAMIN FLUORIDE DROPS		
vitamin a, vitamin c, vitamin d, vitamin e, vitamin b1, vitamin b2, vitamin b12, niacin, vitamin b6, flouride solution		
Product Information		
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source) NDC:52959-593(NDC:64376-820)
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
THIAMINE (UNII: Y66NSQ2N2E) (THIAMINE - UNII:Y66NSQ2N2E)	THIAMINE	0.5 mg

THIAMINE (UNII: X0U1NS03NS3) (THIAMINE - UNII:X0U1NS03NS3)	THIAMINE	in 1 mL
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	0.6 mg in 1 mL
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	35 mg in 1 mL
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU] in 1 mL
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	8 mg in 1 mL
PYRIDOXINE (UNII: KV2JZ1B16Z) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE	0.4 mg in 1 mL
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	2 ug in 1 mL
FLUORIDE ION (UNII: Q80VPU408O) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 mg in 1 mL
.ALPHA.-TOCOPHEROL SUCCINATE, D- (UNII: LU4B53JYVE) (.ALPHA.-TOCOPHEROL SUCCINATE, D- - UNII:LU4B53JYVE)	.ALPHA.-TOCOPHEROL SUCCINATE, D-	5 [iU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0K00R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
GLYCERIN (UNII: PDC6A3C0OX)	
ORANGE OIL (UNII: AKN3KSD11B)	
FERROUS SULFATE (UNII: 39R4TAN1VT)	
CHERRY (UNII: BUC5I9595W)	
CARAMEL (UNII: T9D99G2B1R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-593-50	50 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		05/04/2011	

Registrant - Boca Pharmacal, Inc. (170266089)

Establishment

Name	Address	ID/FEI	Business Operations
Sonar Products, Inc.		104283945	MANUFACTURE

Revised: 10/2011

H.J. Harkins Company, Inc.