

VITAMINS A, C, D AND FLUORIDE DROPS- vitamin a palmitate, ascorbic acid, cholecalciferol, and sodium fluoride solution/ drops
H2-Pharma, LLC

Vitamins A, C, D and Fluoride

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%
Fluoride	0.5 mg	*

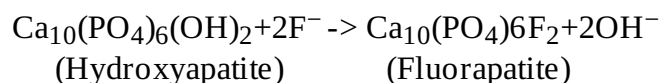
* Daily Value not established

Active ingredient for caries prophylaxis: Fluoride as sodium fluoride.

Other ingredients: Ascorbic acid, caramel color, cholecalciferol, citric acid, ferrous sulfate, flavor, glycerin, methyl paraben, polysorbate 80, purified water, sodium benzoate, sodium hydroxide, sodium fluoride, sucralose, vitamin A palmitate.

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:



Three stages of fluoride deposition in tooth enamel can be distinguished: 1. Small amounts (reflecting the low levels of the 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.

Supplementation of the diet with **Vitamins A, C, D and Fluoride 0.5 mg Drops** also provides 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. **Vitamins A, C, D and Fluoride 0.5 mg Drops** provide fluoride in drop form for 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 for children ages 3-6 years, in areas where the drinking water contains 0.3 through 0.6 ppm of fluoride. Each 1.0 mL supplies sodium fluoride (0.5 mg fluoride) plus three basic vitamins. The American Academy of Pediatrics recommends 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 for children ages 3-6 years, 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 half dose (0.5 mL) of Vitamins A, C, D

and Fluoride 0.5 mg Drops. A comprehensive 5 ½ year series of studies of the effectiveness of multivitamins and fluoride drops in caries protection has been published. Children in this continuing study lived in an area where the water supply contained only 0.05 ppm fluoride. The subjects were divided into two groups: one which used only the non-fluoride vitamin drops, and the other group used multivitamin-fluoride drops. The three year interim report showed 63% fewer carious surfaces in primary teeth and 43% fewer carious surfaces in permanent teeth of the children taking multivitamin-fluoride products. After four years, the studies continued to support the effectiveness of multivitamin-fluoride products, showing a reduction in carious surfaces of 68% in primary teeth and 46% in permanent teeth. Results at the end of the 5 ½ years further confirmed the previous findings and indicated that significant reductions in dental caries are apparent with the continued use of multivitamin-fluoride products. *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. Vitamins A, C, D and Fluoride Supplemental Drops 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.)

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 the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

Use as directed 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

Vitamins A, C, D and Fluoride 0.5 mg Drops 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.

Distributed by: **H2-Pharma, LLC**
Montgomery, AL 36117

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Label

61269-167-50

Vitamins
A, C, D
and Fluoride

Supplement Drops

1 fl. oz. (50 mL)

0.5 mg

H² pharma



Distributed by: H²-Pharma, LLC
Montgomery, AL 36117
www.h2-pharma.com

61269-167-50

**Vitamins
A, C, D
and Fluoride**

Supplement Drops

1²/₃ fl. oz. (50 mL)

0.5 mg



SHAKE WELL

DOSAGE: See carton for dosage and administration information.

USE FULL DOSAGE

*U.S. Recommended Daily Allowance has not been established.

Active Ingredient for caries prophylaxis: Each 1 mL contains 0.5 mg fluoride as sodium fluoride.

Other Ingredients: Ascorbic acid, caramel color, cholecalciferol, citric acid, ferrous sulfate, flavor, glycerin, methyl paraben, polysorbate 80, purified water, sodium benzoate, sodium hydroxide, sodium fluoride, sucralose, vitamin A palmitate.

Tamper Evident: Do not use if seal under cap is torn, broken or missing.

WARNING: KEEP OUT OF REACH OF CHILDREN.

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%
Fluoride	0.5 mg	*
*Daily Value not established		

180062[01]

VITAMINS A, C, D AND FLUORIDE DROPS

vitamin a palmitate, ascorbic acid, cholecalciferol, and sodium fluoride solution/ drops

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:61269-167
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) (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
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU] in 1 mL
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARAMEL (UNII: T9D99G2B1R)	

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FERROUS SULFATE (UNII: 39R4TAN1VT)	
CHERRY (UNII: BUC5I9595W)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:61269-167-50	1 in 1 CARTON		
1		50 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		10/22/2018	

Supplement Facts	
Serving Size :	Serving per Container :
Amount Per Serving	% Daily Value
color	
flavor	

Labeler - H2-Pharma, LLC (028473634)