

**MULTIVITAMIN WITH FLUORIDE - sodium fluoride tablet, chewable**  
**PureTek Corporation**

*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.*

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**Prescribing Information**

**MULTIVITAMIN WITH FLUORIDE vitamin A, ascorbic acid, sodium ascorbate, cholecalciferol, alpha-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid and cyanocobalamin tablet, chewable**  
**Each Fluoride Chewable Tablet Contains:**

**Nutrition Facts**

Dosage Size 1 Chewable Tablet

<b>Amount per tablet</b>	<b>0.25 mg</b>	<b>%DV Adults and Children 4 years or More</b>
Vitamin A	2500 IU	50%
Vitamin C	60 mg	100%
Vitamin D	400 IU	100%
Vitamin E	15 IU	50%
Thiamine	1.05 mg	70%
Riboflavin	1.2 mg	71%
Niacin	13.5 mg	68%
Vitamin B <sub>6</sub>	1.05 mg	53%
Folate	300 mcg	75%
Vitamin B <sub>12</sub>	4.5 mcg	75%
Fluoride	0.25 mg	*

\*daily value (DV) not established

Multivitamin with Fluoride 0.25 mg active ingredient for caries prophylaxis: Fluoride as sodium fluoride

**Multivitamin with 0.25 mg Fluoride Chewable Tablets** provide sodium fluoride and ten essential vitamins in a chewable tablet.

Other ingredients: ascorbic acid, cholecalciferol, compressible sugar, croscarmellose sodium, dl-alpha tocopheryl acetate, D and C Red #27 aluminum lake, FD and C Blue #1 aluminum lake, folic acid, grape flavor, magnesium stearate, microcrystalline cellulose, niacinamide, pyridoxine, riboflavin, sodium ascorbate, stearic acid, thiamine, vitamin A, vitamin B<sub>12</sub>.

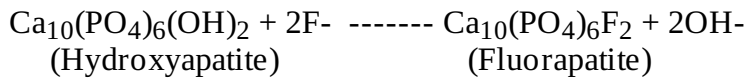
**CLINICAL PHARMACOLOGY**

**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.**

**Multivitamin with 0.25 mg Fluoride Chewable Tablets** provide sodium fluoride and ten essential vitamins in a chewable tablet. Because the tablets are chewable, they provide a *topical* as well as *systemic* source of fluoride.

*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 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 the water, food, supplementary fluoride and smaller amounts from saliva.

### INDICATIONS AND USAGE

Supplementation of the diet with ten essential vitamins.

Supplementation of the diet with fluoride for caries prophylaxis.

**Multivitamin with 0.25 mg Fluoride Chewable Tablets** provide 0.25 mg fluoride in tablet form for children 4-6 years of age in areas where the drinking water contains 0.3 through 0.6 ppm of fluoride.

**Multivitamin with 0.25 mg Fluoride Chewable Tablets** supply significant amounts of Vitamins A, C, D, E, thiamine, riboflavin, niacin, vitamin B<sub>6</sub>, vitamin B<sub>12</sub>, and folate 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 ten essential vitamins and the important mineral, fluoride.

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 supplements.

Children using **Multivitamin with 0.25 mg Fluoride Chewable Tablets** regularly should receive semiannual dental examinations. The regular brushing of teeth and attention to good oral hygiene practices are also essential.

Multivitamin with Fluoride Chewable Tablets is a prescription product for the clinical dietary management of the metabolic processes of caries prophylaxis and provides supplementation of the diet with ten essential vitamins.

### WARNING

**Keep out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.**

Caution: Do not eat or drink dairy products within one hour of fluoride administration.

Should be chewed. This product, as all chewable tablets, is not recommended for children under age 4 due to risk of choking.

## **PRECAUTIONS**

The suggested dose of **Multivitamin with 0.25 mg Fluoride Chewable Tablets** should not be exceeded, since dental fluorosis may result from continued ingestion of large amounts of fluoride.

Before prescribing **Multivitamin with 0.25 mg Fluoride Chewable Tablets**:

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.

## **ADVERSE REACTIONS**

Allergic rash and other idiosyncrasies have been rarely reported.

## **DOSAGE AND ADMINISTRATION**

One tablet daily, to be dissolved in the mouth or chewed before swallowing. Do not give a chewable tablet to a child younger than 4 years old.

## **HOW SUPPLIED**

Multivitamin Chewable tablets containing 0.25 mg fluoride are purple-colored, grape flavor, un-scored, round debossed "107" tablets are available on prescription only in bottles of 100 tablets. NDC: 59088-107-59.

## **STORAGE**

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature.

Dispense in a tight, light resistant container with a child-resistant closure as defined in the USP/NF. All prescription substitutions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

## **Base Label**

Each Chewable Tablet Contains:

Nutrition Facts		
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 Multivitamin with Fluoride 0.25 mg Fluoride Chewable Tablets provide sodium fluoride and ten

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**Other Ingredients:** ascorbic acid, cholecalciferol, compressible sugar, croscarmellose sodium, dl-alpha tocopheryl acetate, D&C Red #27 aluminum lake, FD&C Blue #1 aluminum lake, folic acid, grape flavor, magnesium stearate, microcrystalline cellulose, niacinamide, pyridoxine, riboflavin, sodium ascorbate, stearic acid, thiamine, vitamin A, vitamin B<sub>12</sub>.

◀ Consult Package Insert For Full Prescribing Information.

NDC 59088-107-59

Rx Only

# Multivitamin with Fluoride

## Chewable Tablets

0.25 mg

Grape Flavor

Manufactured by:  
**PureTek Corporation**  
 San Fernando, CA 91340

**PharmaPure**

100 TABLETS

## Inside Label

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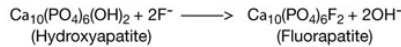
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## Outside label

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**PharmaPure**

Manufactured By:  
**PureTek Corporation**  
 San Fernando, CA 91340

List No. 10759 ENA  
 Rev. 01 240181-1

NDC 59088-107-59

Rx Only

# Multivitamin with Fluoride

## Chewable Tablets

0.25 mg

Grape Flavor

Manufactured by:  
**PureTek Corporation**  
 San Fernando, CA 91340

**PharmaPure**

100 TABLETS

Enter section text here

## MULTIVITAMIN WITH FLUORIDE

sodium fluoride tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:59088-107
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 mg
<b>VITAMIN A</b> (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	2500 [iU]
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	24 mg
<b>SODIUM ASCORBATE</b> (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	SODIUM ASCORBATE	36 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (ALPHA-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL ACETATE, DL-	15 [iU]
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE - UNII:X66NSO3N35)	THIAMINE	1.05 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.2 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	13.5 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	1.05 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	300 ug
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug

### Inactive Ingredients

Ingredient Name	Strength
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	purple (Dark purple)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>	GRAPE (Grape flavor)	<b>Imprint Code</b>	107
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-107-59	100 in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2011	

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**Labeler** - PureTek Corporation (785961046)

**Establishment**

Name	Address	ID/FEI	Business Operations
PureTek Corporation		78596 1046	manufacture, label, pack, outsourcing human drug compounding, relabel, repack

Revised: 5/2011

PureTek Corporation