

**DAVIMET WITH FLUORIDE- multivitamin, 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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**Davimet with Fluoride**

**Description:**

**Each Chewable Tablet Contains:**

|  |  |
|--|--|
| Vitamin A (as Retinyl Acetate).....                                | 750 mcg RAE                                    |
| Vitamin C (as Sodium Ascorbate 36 mg and Ascorbic Acid 24 mg)..... | 60 mg  |
| Vitamin D3 (as Cholecalciferol).....                               | 10 mcg (400IU)                                 |
| Vitamin E (as DL-Alpha Tocopheryl Acetate).....                    | 6.75 mg  |
| Thiamin (as Thiamine Mononitrate).....                             | 1.05 mg  |
| Riboflavin.....  | 1.2 mg   |
| Niacin (as Niacinamide).....                                       | 13.5 mg  |
| Vitamin B6 (as Pyridoxine Hydrochloride).....                      | 1.05 mg  |
| Folate (as L-5-Methyltetrahydrofolate calcium salt).....           | 1700 mcg DFE<br>(1000 mcg as L-5-Methylfolate) |
| Vitamin B12 (as Methylcobalamin).....                              | 4.5 mcg  |
| Fluoride (as Sodium Fluoride) .....                                | 0.75 mg  |

**Davimet™ with Fluoride 0.75 mg Chewable Multivitamin active ingredient for caries prophylaxis:** Fluoride as sodium fluoride.

**Davimet™ with Fluoride 0.75 mg Chewable Multivitamin** provide sodium fluoride and ten essential vitamins in a chewable tablet.

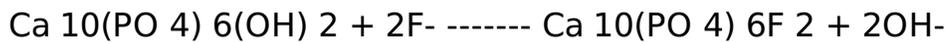
**Other Ingredients:** Aspartame, Croscarmellose Sodium, Natural Grape Flavor, Magnesium Stearate (Vegetable Source), Maltodextrin, Microcrystalline Cellulose, Stearic Acid (Vegetable Source), Sucrose, CI 45410 (Red 27 Lake), CI 42090 (FD&C Blue No. 1 Aluminum Lake).

**Phenylketonurics: Contains Phenylalanine 3.0 mg Per Tablet.**

**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.

**Davimet™ with Fluoride 0.75 mg Chewable Multivitamin** 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:



(Hydroxyapatite) (Fluorapatite)

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.

**Contraindications:** This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

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

**Davimet™ with Fluoride 0.75 mg Chewable Multivitamin** provide 0.75 mg fluoride in tablet form for children 6-16 years of age in areas where the drinking water fluoride level is less than 0.3 ppm.

**Davimet™ with Fluoride 0.75 mg Chewable Multivitamin** supply significant amounts of Vitamins A, C, D, E, thiamine, riboflavin, niacin, vitamin B6, vitamin B12, 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.

Children using **Davimet™ with Fluoride 0.75 mg Chewable Multivitamin** regularly should receive semiannual dental examinations. The regular brushing of teeth and attention to good oral hygiene practices are also essential.

**Davimet™ with Fluoride 0.75 mg Chewable Multivitamin** 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 **Davimet™ with Flouride 0.75 mg Chewable Multivitamin** should not be exceeded, since dental fluorosis may result from continued ingestion of large amounts of fluoride.

Before prescribing **Davimet™ with Flouride 0.75 mg Chewable Multivitamin**:

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.

Folate in doses above 0.1 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive. There is a potential danger in administering folate to patients with undiagnosed anemia, since folate may obscure the diagnosis of pernicious anemia by alleviating the hematologic manifestations of the disease while allowing the neurologic complications to progress. This may result in severe nervous system damage before the correct diagnosis is made. Adequate doses of vitamin B12 may prevent, halt, or improve the neurologic changes caused by pernicious anemia. The patient's medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

## **Adverse Reactions:**

Folate: Allergic sensitization has been reported following both oral and parenteral administration of folate. Adverse reactions have been reported with specific vitamins and minerals but generally at levels substantially higher than those contained herein. However, allergic and idiosyncratic reactions are possible at lower levels.

## **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:**

**Davimet™ with Flouride 0.75 mg Chewable Multivitamin** are light purple with speckles, grape flavored, un-scored, round tablets. Available on prescription only in bottle of 30 tablets - NDC 59088-170-54.

## Storage:

Store at 20° to 25°C (68° to 77°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.

## Davimet™ with Flouride 0.75 mg Chewable Multivitamin

Manufactured in the USA by:

**PureTek Corporation**

Panorama City, CA 91402

Questions? Call toll-free:

**1-877-921-7873**

BL4 - MINIMUM NO. VARNISH  
AREA = 12.5 mm x 38 mm  
FOR POSITION ONLY  
DO NOT PRINT

| Supplement Facts  |                    |               |
|---|--------------------|---------------|
| Serving Size: 1 Tablet  |                    |               |
| Servings per container: 30  |                    |               |
|   | Amount Per Serving | % Daily Value |
| Vitamin A (as Retinyl Acetate)  | 750 mcg RAE        | 83%           |
| Vitamin C (as Sodium Ascorbate 36 mg and Ascorbic Acid 24 mg)                         | 60 mg              | 67%           |
| Vitamin D3 (as Cholecalciferol)   | 10 mcg (400 IU)    | 50%           |
| Vitamin E (as DL-Alpha Tocopheryl Acetate)  | 6.75 mg            | 45%           |
| Thiamin (as Thiamine Mononitrate)   | 1.05 mg            | 88%           |
| Riboflavin  | 1.2 mg             | 92%           |
| Niacin (as Niacinamide)   | 13.5 mg            | 84%           |
| Vitamin B6 (as Pyridoxine Hydrochloride)  | 1.05 mg            | 62%           |
| Folate (as L-5-Methyltetrahydrofolate calcium salt)<br>(1000 mcg of L-5-methylfolate) | 1700 mcg DFE       | 425%          |
| Vitamin B12 (as Methylcobalamin)  | 4.5 mcg            | 188%          |
| Fluoride (as Sodium Fluoride)   | 0.75 mg            | *             |
| * Daily Value not established   |                    |               |

Davimet™ with Flouride 0.75 mg Chewable Multivitamin active ingredient for caries prophylaxis: Fluoride as sodium fluoride. Davimet™ with Flouride 0.75 mg Chewable Multivitamin provide ten essential vitamins in a chewable tablet.

**Other Ingredients:** Aspartame, Croscarmellose Sodium, Natural Grape Flavor, Magnesium Stearate (Vegetable Source), Maltodextrin, Microcrystalline Cellulose, Stearic Acid (Vegetable Source), Sucrose, CI 45410 (Red 27 Lake), CI 42090 (FD&C Blue No. 1 Aluminum Lake).

**Phenylethanolics: Contains Phenylalanine 3.0 mg Per Tablet. Use only under the direction of a licensed healthcare practitioner.**

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

**Manufactured in the USA by:**  
**PureTek Corporation**  
Panorama City, CA 91402  
Questions? Call toll-free:  
**1-877-921-7873**  
Consult Package Insert For Full Prescribing Information.  
List No: 17054IFA Rev. No: 38940

NDC 59088-170-54 Rx Only

**DERMACINRx**

**Davimet™**  
**with Fluoride**

**0.75 mg**

**Chewable Multivitamin**  
Grape Flavor 30 Tablets



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59088 17054  
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## DAVIMET WITH FLUORIDE

multivitamin, fluoride tablet, chewable

### Product Information

|                                |                         |                           |               |
|--------------------------------|-------------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:59088-170 |
| <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            | 0.75 mg  |
| <b>VITAMIN A</b> (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)                                     | VITAMIN A               | 750 ug   |
| <b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)                             | ASCORBIC ACID           | 24 mg    |
| <b>SODIUM ASCORBATE</b> (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)                          | ASCORBIC ACID           | 36 mg    |
| <b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)                         | CHOLECALCIFEROL         | 10 ug    |
| <b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01) | .ALPHA.-TOCOPHEROL, DL- | 6.75 mg  |
| <b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)                       | THIAMINE                | 1.05 mg  |

|   |                      |         |
|---|----------------------|---------|
| <b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)                 | RIBOFLAVIN           | 1.2 mg  |
| <b>NIACIN</b> (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)                         | NIACIN               | 13.5 mg |
| <b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)   | PYRIDOXINE           | 1.05 mg |
| <b>LEVOMEFOLATE CALCIUM</b> (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC) | LEVOMEFOLATE CALCIUM | 1000 ug |
| <b>METHYLCOBALAMIN</b> (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)       | METHYLCOBALAMIN      | 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: H3R47K3TBD)         |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)          |          |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U) |          |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                |          |
| <b>ASPARTAME</b> (UNII: Z0H242BBR1)                   |          |
| <b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)                |          |

### Product Characteristics

|                 |                                     |                     |          |
|-----------------|-------------------------------------|---------------------|----------|
| <b>Color</b>    | purple (Light purple with speckles) | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND                               | <b>Size</b>         | 13mm     |
| <b>Flavor</b>   | GRAPE (Grape flavor)                | <b>Imprint Code</b> |          |
| <b>Contains</b> |                                     |                     |          |

### Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59088-170-54 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/28/2024           |                    |

### Marketing Information

| Marketing Category       | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug<br>other |  | 02/28/2024           |                    |

**Labeler** - PureTek Corporation (785961046)