

**DAVIMET WITH IRON- iron, folate tablet**  
**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 Iron**

**DESCRIPTION:**

Each caplet 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 (400 IU)
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 (1000 mcg as L-5-Methylfolate)	
Vitamin B12 (as Methylcobalamin).....	4.5 mcg
Iron (as Iron Amino Acid Chelate).....	11 mg

Other Ingredients: Aspartame, CI 15985 / [Yellow 6 Lake], Croscarmellose Sodium, Magnesium Stearate, Maltodextrin, Microcrystalline Cellulose, Natural OrangeFlavor, Stearic Acid (Vegetable Source), Sucrose.

Phenylketonurics: Phenylalanine 3.0 mg Per Tablet.

**INDICATIONS AND USAGE:**

**Davimet™ with Iron Multivitamin Chewable Tablets** are indicated for the treatment of iron deficiency anemia and folate deficiency, commonly seen in conditions such as extended convalescence, menorrhagia, pregnancy, puberty, excessive blood loss, and advanced age. They are also indicated for condition in which iron deficiency and vitamin C deficiency occur together, along with a deficient intake or increased need for B-Complex vitamins in chronic and acute illness, as well as cases of metabolic stress, and in convalescence.

**CONTRAINDICATIONS:**

This product is contraindicated in patients with known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemias. Pernicious anemia is a contraindication, as folic acid may obscure its signs and symptoms.

## **WARNING:**

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

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Administration of folate alone is improper therapy for pernicious anemia and other megaloblastic anemias in which vitamin B12 is deficient.

**CAUTION:** Should be chewed.

## **PRECAUTIONS:**

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.

**Use only under the direction of a licensed healthcare practitioner.** Call your doctor about side effects. To report side effects, call **PureTek Corporation** at **1-877-921-7873** or **FDA** at **1-800-FDA-1088** or **[www.fda.gov/medwatch](http://www.fda.gov/medwatch)**.

## **Drug Interactions:**

**Davimet™ with Iron Multivitamin Chewable Tablets** are not recommended and should not be given to patients receiving levodopa because the action of levodopa is antagonized by pyridoxine. There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g., Aspirin, Heparin or Clopidogrel).

## **Adverse Reactions:**

Folate: Allergic sensitizations have been reported following both oral and parenteral administration of folate.

Iron: Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation) occur occasionally, but are usually mild and may subside with continuation of therapy. Although the absorption of iron is best when taken between meals, giving **Davimet™ with Iron Multivitamin Chewable Tablets** after meals may control occasional gastrointestinal disturbances. **Davimet™ with Iron Multivitamin Chewable Tablets** is best absorbed when taken at bedtime.

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. Iron, even at the usual recommended levels, has been associated with gastrointestinal intolerance in some patients

### **OVERDOSE:**

Iron: Signs and Symptoms: Iron is toxic. Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300 mg/kg body weight. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. **Davimet™ with Iron Multivitamin Chewable Tablets** should be stored beyond the reach of children to prevent against accidental iron poisoning.

### **Treatment:**

For specific therapy, exchange transfusion and chelating agents should be used. For general management, perform gastric lavage with sodium bicarbonate solution or milk. Administer intravenous fluids and electrolytes and use oxygen.

### **DOSAGE AND ADMINISTRATION:**

One tablet daily, to be dissolved in the mouth or chewed before swallowing.

**Do not use if bottle seal is broken.**

**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

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

### **HOW SUPPLIED:**

**Davimet™ with Iron Multivitamin Chewable Tablets** are light orange with speckles, orange flavor, un-scored, round tablets. Available on prescription only in bottle of 30 tablets - NDC 59088-160-54. 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 Iron**

**Manufactured by:**

**PureTek Corporation**

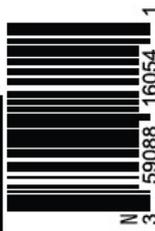
Panorama City, CA 91402

For questions or information

call toll-free: **877-921-7873**

**Dosage and Administration:** One tablet daily, to be dissolved in the mouth or chewed before swallowing.  
**Davimet™ with Iron Multivitamin Chewable Tablets** provide ten essential vitamins and Iron in a chewable tablet.  
**Phenylketonurics: 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].  
 List No: 16054IFA Rev. No: 38602-01  
**Manufactured in the USA by:**  
**PureTek Corporation**  
 Panorama City, CA 91402  
 Questions? Call toll-free:  
**1-877-921-7873**

**WARNING:** Accidental overdose of Iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.



**Active Ingredients:**  
**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 (400 IU)  
 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 1700 mcg DFE  
 (as L-5-Methyltetrahydrofolate calcium salt)...(1000 mcg as L-5-Methylfolate)  
 Vitamin B12 (as Methylcobalamin)..... 4.5 mcg  
 Iron (as Iron Amino Acid Chelate)..... 11 mg  
**Other Ingredients:** Aspartame, CI 15985 / [Yellow 6 Lake], Croscarmellose Sodium, Magnesium Stearate, Maltodextrin, Microcrystalline Cellulose, Natural Orange Flavor, Stearic Acid (Vegetable Source), Sucrose.

NDC 59088-160-54

Rx Only

**DERMACIN<sup>®</sup>**  
**Davimet™**  
**with Iron**

**Multivitamin**  
**Chewable Tablets**

**Orange Flavor**

**30 Tablets**

## DAVIMET WITH IRON

iron, folate tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:59088-160
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>VITAMIN A ACETATE</b> (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	750 ug
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	24 mg
<b>NIACINAMIDE</b> (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	13.5 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	1.05 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.05 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
<b>IRON</b> (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	11 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.2 mg
<b>METHYLCOBALAMIN</b> (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	4.5 ug
<b>SODIUM ASCORBATE</b> (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	36 mg
<b>LEVOMEFOLATE CALCIUM</b> (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	1000 ug
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	6.75 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	

**Product Characteristics**

<b>Color</b>	orange (Light Orange with Speckles)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-160-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/03/2024	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/03/2024	

**Labeler** - PureTek Corporation (785961046)