

**DAVITE- ascorbic acid, thiamine, riboflavin, niacinamide, pyridoxine, folic acid, cyanocobalamin, biotin, pantothenic acid tablet, coated**  
**SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS**

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**DaVite Tablets**

**ascorbic acid, thiamine, riboflavin, niacinamide, pyridoxine, folic acid, cyanocobalamin, biotin, pantothenic acid**

**Rx Only**

**DESCRIPTION**

DaVite is a prescription folic acid supplement with additional nutrients for kidney dialysis patients. DaVite is a small, round, yellow tablet

**Each tablet contains:**

Vitamin C (Ascorbic Acid).....100 mg

Vitamin B1 (Thiamine).....1.5 mg

Vitamin B2 ( Riboflavin) .....1.7 mg

Vitamin B3 (Niacinamide).....20 mg

Vitamin B6 (Pyridoxine HCl).....10 mg

Folic Acid.....1000 mcg

Vitamin B12 (Cyanocobalamin).....6 mcg

Biotin.....150 mcg

Pantothenic Acid .....5 mg

**Inactive ingredients:**

Microcrystalline Cellulose, Dicalcium Phosphate, Stearic Acid, Croscarmellose Sodium, Magnesium Stearate, Silicon Dioxide, Opadry II Yellow (color).

**INDICATIONS AND USAGE**

DaVite is a prescription folic acid supplement with additional nutrients indicated for use in improving the nutritional status of renal dialysis patients.

**CONTRAINDICATIONS**

This product is contraindicated in patients with known hypersensitivity to any of the ingredients.

**WARNING**

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. **KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN.** In case of accidental overdose, call a doctor or poison control center immediately.

**PRECAUTIONS**

**Folic Acid**

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. Pernicious anemia should be excluded before using these products since folic acid may mask the symptoms of pernicious anemia.

**Pediatric Use**

Safety and effectiveness in pediatric patients have not been established.

### **Geriatric Use**

Dosing for elderly patients should be cautious. Due to the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy, dosing should start at the lower end of the dosing range.

### **ADVERSE REACTIONS**

Adverse reactions with iron therapy may include GI irritation, constipation, diarrhea, nausea, vomiting, and dark stools. Adverse reactions with iron therapy are usually transient. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

### **DRUG INTERACTIONS**

Prescriber should be aware of a number of iron/drug interactions, including antacids, tetracyclines, or fluoroquinolones.

### **OVERDOSAGE**

Symptoms: abdominal pain, metabolic acidosis, anuria, CNS damage, coma, convulsions, death, dehydration, diffuse vascular congestion, hepatic cirrhosis, hypotension, hypothermia, lethargy, nausea, vomiting, diarrhea, tarry stools, melena, hematemesis, tachycardia, hyperglycemia, drowsiness, pallor, cyanosis, lassitude, seizures, and shock.

### **DOSAGE AND ADMINISTRATION**

One tablet daily or as directed by a physician.

**NOTICE** Contact with moisture can discolor or erode the tablet. Do not chew tablet.

### **STORAGE**

Store at 20°-25°C (66°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.] Protect from heat, light and moisture.

### **HOW SUPPLIED**

Bottles of 90 tablets each - NDC 73317-4826-9

DaVite Tablets

Multivitamin Supplement for Dialysis Patients

To report a serious adverse event or obtain product information, call (866)-760-6565

**Call your licensed medical practitioner about side effect.**

**You may report side effects by calling AUM 866-760-6565.**

**Manufactured and Distributed by:**

AUM Pharmaceuticals  
Hauppauge, NY 11788.

**Made in USA**

**STORAGE:**

Store at room temperature at 20° - 25°C (66° - 77°F) Excursions permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature].

**Protect from Heat, Light and Moisture.**

See package insert for full prescribing information.

**WARNING:**

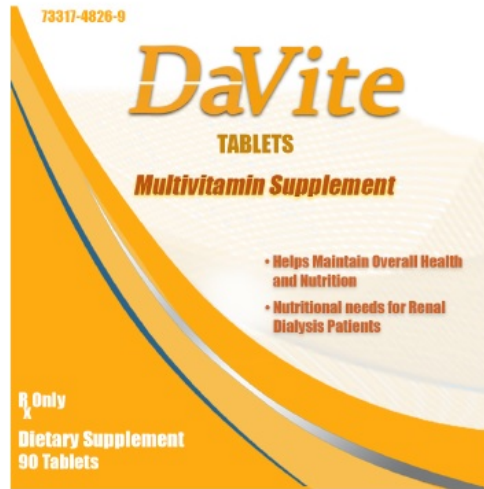
If you are pregnant, nursing or taking medication, consult your doctor before use. In case of accidental overdose, call a doctor or poison control center immediately.

**DO NOT USE IF SEAL UNDER CAP IS BROKEN**

Call your Licensed medical practitioner about side effects. You may report side effects by calling AUM Pharmaceuticals: 1-866-760-6565

**Manufactured & Distributed By:**

AUM Pharmaceuticals  
Hempstead, NY 11788  
MADE IN USA

**EACH TABLET CONTAINS:**

Serving Size: One (1) Tablet

Vitamin C (Ascorbic Acid)	100 MG
Vitamin B1 (As Thiamine Mononitrate)	1.5 MG
Vitamin B2 (Riboflavin)	1.7 MG
Vitamin B3 (As Niacinamide)	20 MG
Vitamin B6 (As Pyridoxine HCl)	10 MG
Folic Acid	1000 MCG
Vitamin B12 (As Cyanocobalamin) on DCP	6 MCG
Biotin On Dicalcium Phosphate	150 MCG
Pantothenic Acid	5 MG

**OTHER INGREDIENTS:**

Microcrystalline Cellulose, Dicalcium Phosphate, Stearic Acid, Croscarmellose Sodium, Magnesium Stearate, Silicon Dioxide, Opady II Yellow.

**SUGGESTED USE:**

Take one tablet daily with food or as directed by a physician. Keep bottle tightly closed. Store in cool dry place.

**KEEP OUT OF REACH OF CHILDREN**

**DAVITE**

ascorbic acid, thiamine, riboflavin, niacinamide, pyridoxine, folic acid, cyanocobalamin, biotin, pantothenic acid tablet, coated

**Product Information**

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRC:73317-4826
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Ascorbic Acid</b> (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	100 mg
<b>Thiamine Mononitrate</b> (UNII: 8K0I04919X) (Thiamine Ion - UNII:4ABT0J945J)	Thiamine	1.5 mg
<b>Riboflavin</b> (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	1.7 mg
<b>Niacinamide</b> (UNII: 25X51I8RD4) (Niacinamide - UNII:25X51I8RD4)	Niacinamide	20 mg
<b>Pyridoxine Hydrochloride</b> (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine	10 mg
<b>Folic Acid</b> (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1000 ug
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	6 ug
<b>Biotin</b> (UNII: 6SO6U10H04) (Biotin - UNII:6SO6U10H04)	Biotin	150 ug
<b>PANTOTHENIC ACID</b> (UNII: 19F5HK2737) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	5 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>Microcrystalline Cellulose</b> (UNII: OP1R32D61U)	
<b>CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: L11K75P92J)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>Croscarmellose Sodium</b> (UNII: M28OL1HH48)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:73317-4826-9	90 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		04/20/2020	

Supplement Facts	
Serving Size :	Serving per Container :
Amount Per Serving	% Daily Value
color	
shape	
size (solid drugs)	11 mm
scoring	1

**Labeler** - SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS (081225162)

Establishment			
Name	Address	ID/FEI	Business Operations
SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS		081225162	

Revised: 4/2020

SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS