

**DAYAVITE- coenzyme q10, alpha-lipoic acid, ascorbic acid, beta-carotene, cholecalciferol, chromium, copper, d-alpha tocopheryl acid, folic acid, magnesium, manganese, methylcobalamin, molybdenum amino acid, niacinamide, potassium, pyridoxine, riboflavin, selenium, thiamine, zinc tablet, coated**  
**Amella Pharma, Llc**

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## DAYAVITE

**HEALTH CLAIM:**  
**DAYAVITE Tablets Dietary Supplement**

**Dispensed by Prescription†**

<b>Supplement Facts</b>		
Serving Size:1 Tablet		Serving per container: 30
<b>Amount Per Serving</b>		<b>% Daily Value</b>
Vitamin A (as Retinyl Palmitate, Beta-Carotene)	750 mcg	83%
Vitamin C (as Ascorbic Acid, Acerola Fruit Extract)	75 mg	83%
Vitamin D (as Cholecalciferol)	25 mcg (1000 IU)	125%
Vitamin E (as D-Alpha Tocopheryl Acid Succinate)	20.1 mg	134%
Thiamine (as Thiamine Mononitrate)	15 mg	1250%
Riboflavin	15 mg	1154%
Niacin (as Niacinamide)	20 mg	125%
Vitamin B6 (as Pyridoxine HCl)	17.5 mg	1029%
Folate	1666 mcg DFE (1 mg Folic Acid)	417%
Vitamin B12 (as Methylcobalamin)	50 mcg	2083%
Iodine (as Potassium Iodide)	75 mcg	50%
Magnesium (as Magnesium Oxide)	200 mg	48%
Zinc (as Zinc Gluconate)	7.5 mg	68%
Selenium (as Selenium Chelate)	35 mcg	64%
Copper (as Copper Bisglycinate Chelate)	1 mg	111%
Manganese (as Manganese Bisglycinate Chelate)	2.5 mg	109%
Chromium (as Chromium	100 mcg	200%

Polynicotinate)	100 mcg	200 %
Molybdenum (as Molybdenum Amino Acid Chelate)	37.5 mcg	83%
Alpha-Lipoic Acid	75 mg	**
Coenzyme Q10	10 mg	**
** Daily Value not established		

**OTHER INGREDIENTS:** Croscarmellose Sodium, Film Coating (Polyvinyl Alcohol, Polyethylene Glycol, Titanium Dioxide, Talc, FD&C Red #40, FD&C Yellow #6), Stearic Acid, Calcium Carbonate, Pharmaceutical Glaze, Microcrystalline Cellulose, Magnesium Stearate, Mono-and Diglycerides, Silicon Dioxide.

## DESCRIPTION

DAYAVITE Tablets is an orally administered prescription vitamin formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced folate supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good health is needed.

DAYAVITE is a long, oblong, dark pink, clear-coated tablet, with debossed "A3" on one side.

## CONTRAINDICATIONS

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

## PRECAUTIONS

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

DAYAVITE Tablets should only be used under the direction and supervision of a licensed medical practitioner. Use with caution in patients that may have a medical condition, are pregnant, lactating, trying to conceive, under the age of 18, or taking medications.

Folic acid supplementation may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations progress.

## WARNINGS

### KEEP OUT OF REACH OF CHILDREN.

#### Pregnancy and Lactation:

DAYAVITE Tablets is not intended for use in pregnant or lactating patients.

## ADVERSE REACTIONS

Allergic sensitizations have been reported following oral administration of folic acid. Consult your physician immediately if adverse side effects occur.

## DOSAGE AND ADMINISTRATION

Usual adult dose is 1 tablet by mouth once daily or as prescribed by a licensed medical

practitioner.

### **HOW SUPPLIED HEALTH CLAIM:**

DAYAVITE Tablets are supplied as a long, oblong, dark pink, clear-coated tablet, with debossed "A3" on one side.

DAYAVITE Tablets is available as the following:

72287-0663-30\* 30ct bottle

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

Manufactured for:  
Amella Pharma, LLC  
E Brunswick, NJ 08816

Call your doctor for medical advice about side effects. You may report side effects to Amella Pharma, LLC at 1-844-385-0850.

Issued: 04/2021 AP11002v1

\*Amella Pharma does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.

† This product is a prescription-folate with or without other dietary ingredients that – due to increased folate levels increased risk associated with masking of B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (61 FR 8760). The most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product only by prescription (Rx). This is not an Orange Book product. This product may be administered only under a physician's supervision and all prescriptions using this product shall be pursuant to state statutes as applicable. The ingredients, indication or claims of this product are not to be construed to be drug claims.

1. Federal Register Notice of August 2, 1973 (38 FR 20750)
2. Federal Register Notice of October 17, 1980 (45 FR 69043, 69044)
3. Federal Register Notice of March 5, 1996 (61 FR 8760)

### **Packaging**

USUAL DOSAGE: Usual adult dose is 1 tablet by mouth once daily or as prescribed by a licensed medical practitioner. If you are pregnant or nursing, ask a healthcare professional prior to using. Consult your physician immediately if adverse side effects occur.

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



VARNISH FREE ZONE FOR EXPIRATION AND LOT #

03/2021 AP11003v1  
**Amella Pharma**  
Manufactured for:  
Amella Pharma, LLC  
East Brunswick, NJ 08816  
1-844-385-0850

72287-0663-30

**DAYAVITE** Tablets



30 Tablets Rx Only

KEEP OUT OF REACH OF CHILDREN

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Selenium (as Selenium Chelate)	35 mcg	64%
Copper (as Copper Bisglycinate Chelate)	1 mg	111%
Manganese (as Manganese Bisglycinate Chelate)	2.5 mg	109%
Chromium (as Chromium Polynicotinate)	100 mcg	286%
Molybdenum (as Molybdenum Amino Acid Chelate)	37.5 mcg	83%
Alpha-Lipoic Acid	75 mg	**
Coenzyme Q10	10 mg	**
** Daily Value not established		

OTHER INGREDIENTS: Croscarmellose Sodium, Film Coating (Polyvinyl Alcohol, Polyethylene Glycol, Titanium Dioxide, Talc, FD&C Red #40, FD&C Yellow #6), Stearic Acid, Calcium Carbonate, Pharmaceutical Glaze, Microcrystalline Cellulose, Magnesium Stearate, Mono- and Diglycerides, Silicon Dioxide.

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## DAYAVITE

coenzyme q10, alpha-lipoic acid, ascorbic acid, beta-carotene, cholecalciferol, chromium, copper, d-alpha tocopheryl acid, folic acid, magnesium, manganese, methylcobalamin, molybdenum amino acid, niacinamide, potassium, pyridoxine, riboflavin, selenium, thiamine, zinc tablet, coated

### Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:72287-663
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	750 ug
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	75 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	25 ug
<b>.ALPHA.-TOCOPHEROL SUCCINATE, D-</b> (UNII: LU4B53JYVE) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL SUCCINATE, D-	20.1 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	15 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	15 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	17.5 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>METHYLCOBALAMIN</b> (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	50 ug
<b>POTASSIUM IODIDE</b> (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	75 ug
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	200 mg
<b>ZINC GLUCONATE</b> (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC GLUCONATE	7.5 mg
<b>SELENIUM</b> (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	35 ug
<b>COPPER</b> (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	1 mg
<b>MANGANESE</b> (UNII: 42Z2K6ZL8P) (MANGANESE - UNII:42Z2K6ZL8P)	MANGANESE	2.5 mg
<b>CHROMIUM NICOTINATE</b> (UNII: A150AY412V) (NIACIN - UNII:2679MF687A)	CHROMIUM NICOTINATE	100 ug
<b>MOLYBDENUM</b> (UNII: 81AH48963U) (MOLYBDENUM - UNII:81AH48963U)	MOLYBDENUM	37.5 ug
<b>ALPHA LIPOIC ACID</b> (UNII: 73Y7P0K73Y) (.ALPHA.-LIPOIC ACID - UNII:73Y7P0K73Y)	ALPHA LIPOIC ACID	75 mg
<b>UBIDECARENONE</b> (UNII: EJ27X76M46) (UBIDECARENONE - UNII:EJ27X76M46)	UBIDECARENONE	10 mg

Inactive Ingredients	
Ingredient Name	Strength
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>GLYCERYL MONO AND DIPALMITOSTEARATE</b> (UNII: KC98RO82HJ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:72287-663-30	30 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
dietary supplement			04/14/2021	

Supplement Facts		
Serving Size :		Serving per Container :
	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	19 mm	
scoring	1	
imprint		

**Labeler** - Amella Pharma, Llc (081189492)

Revised: 4/2021

Amella Pharma, Llc