

**DIALYVITE 3000 - ascorbic acid, tocopheryl acid succinate, thiamine, riboflavin, niacinamide, pyridoxine, folic acid, cobalamin, biotin, pantothenic acid, zinc, selenium tablet, coated**  
**Hillestad Pharmaceuticals USA**

*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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**Dialyvite 3000**

**DESCRIPTION**

Dialyvite 3000 is a prescription folic acid supplement with additional nutrients for kidney dialysis patients. Dialyvite 3000 is a small, round, light brown, clear-coated tablet, with debossed "H" on one side.

**Each tablet contains:**

Folic Acid.....3 mg

Vitamin E (d-alpha Tocopheryl Acid Succinate).....30 IU

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

Thiamine (Thiamine Mononitrate).....1.5 mg

Riboflavin.....1.7 mg

Niacinamide.....20 mg

Vitamin B6 (Pyridoxine HCl).....25 mg

Vitamin B12 (Methylcobalamin).....1 mg

Biotin.....300 mcg

Pantothenic Acid (Calcium Pantothenate).....10 mg

Zinc (Zinc Citrate).....15 mg

Selenium (Selenium Amino Acid Chelate).....70 mcg

**Inactive ingredients:**

Microcrystalline Cellulose, Croscarmellose Sodium, Mono-and Diglycerides, Pharmaceutical Glaze, Carob (color), Starch, Calcium Stearate, Silicon Dioxide.

**INDICATIONS AND USAGE**

Dialyvite 3000 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.

## PRECAUTIONS

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

Keep out of reach of children.

## 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

Take one tablet per day or use as directed by your physician, orally.

## PRINCIPAL DISPLAY PANEL

NDC 10542-014-09

Dialyvite 3000

Multivitamin Supplement for Dialysis Patients

90 Tablets

Use as directed by your physician.

Water-soluble B Vitamins and Vitamin C for use as a dietary supplement.

Consult your physician immediately if adverse side effects occur.

### KEEP OUT OF REACH OF CHILDREN

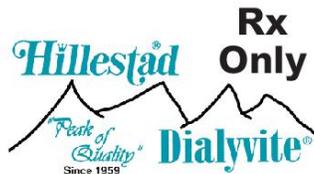
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NDC 10542-014-09

# Dialyvite® 3000

Multi-Vitamin Supplement  
for Dialysis Patients

90  
Tablets



Supplement Facts	
Serving Size 1 Tablet	Servings Per Container 90
Amount Per Tablet	% Daily Value
Vitamin C (as Ascorbic Acid) .....	100 mg..... 111%
Vitamin E (as d-Alpha Tocopheryl Acid Succinate) 20 mg.....	133%
Thiamine (as Thiamine Mononitrate).....	1.5 mg..... 125%
Riboflavin.....	1.7 mg..... 131%
Niacin (as Niacinamide) .....	20 mg..... 125%
Vitamin B6 (as Pyridoxine HCl) .....	25 mg..... 1471%
Folate.....	5000 mcg DFE..... 1250%
	(3 mg Folic Acid)
Vitamin B12 (as Methylcobalamin).....	1 mg . 41667%
Biotin.....	300 mcg.... 1000%
Pantothenic Acid (as D-Calcium Pantothenate) ..	10 mg..... 200%
Zinc (as Zinc Citrate).....	15 mg ..... 136%
Selenium (as Selenium Amino Acid Chelate) ....	70 mcg ..... 127%

Other ingredients: Microcrystalline Cellulose, Croscarmellose Sodium, Mono- and Diglycerides, Pharmaceutical Glaze, Carob (color), Starch, Silicon Dioxide, Calcium Stearate.

(Rev. 6)

Product #HP14



**DIALYVITE 3000**

ascorbic acid, tocopheryl acid succinate, thiamine, riboflavin, niacinamide, pyridoxine, folic acid, cobalamin, biotin, pantothenic acid, zinc, selenium tablet, coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:10542-014
<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:KV2JZ1B16Z)	Pyridoxine	25 mg
<b>Folic Acid</b> (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	3 mg
<b>Cobalamin</b> (UNII: 8406EY2OQA) (Cobalamin - UNII:8406EY2OQA)	Cobalamin	1 mg
<b>Biotin</b> (UNII: 6S06U10H04) (Biotin - UNII:6S06U10H04)	Biotin	300 ug
<b>Calcium Pantothenate</b> (UNII: 568ET80C3D) (Pantothenic Acid - UNII:19F5HK2737)	Pantothenic Acid	10 mg
<b>Zinc Citrate</b> (UNII: K72I3DEX9B) (Zinc Cation - UNII:13S1S8SF37)	Zinc Cation	15 mg
<b>.alpha.-tocopherol succinate, d-</b> (UNII: LU4B53JYVE) (.alpha.-tocopherol, d- - UNII:N9PR3490H9)	.alpha.-tocopherol, d-	30 [IU]
<b>Selenocysteine</b> (UNII: 0CH9049VIS) (Selenium - UNII:H6241UJ22B)	Selenium	70 ug

### Inactive Ingredients

Ingredient Name	Strength
<b>Microcrystalline Cellulose</b> (UNII: OP1R32D61U)	
<b>Croscarmellose Sodium</b> (UNII: M28OL1HH48)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>Carob</b> (UNII: 5MG5Z946UO)	
<b>Shellac</b> (UNII: 46N107B71O)	
<b>Starch, Corn</b> (UNII: O8232NY3SJ)	
<b>Calcium Stearate</b> (UNII: 776XM7047L)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	

### Product Characteristics

<b>Color</b>	brown	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	H
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

<b>1</b>	NDC:10542-014-09	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2004	07/31/2026
<b>2</b>	NDC:10542-014-02	7 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2004	07/31/2026

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		02/01/2004	07/31/2026

**Labeler** - Hillestad Pharmaceuticals USA (029291085)

## Establishment

Name	Address	ID/FEI	Business Operations
Hillestad Pharmaceuticals USA		029291085	manufacture(10542-014) , pack(10542-014) , label(10542-014)

Revised: 1/2027

Hillestad Pharmaceuticals USA