

DIALYVITE 5000 - 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.

Dialyvite 5000

DESCRIPTION

Dialyvite 5000 is a prescription folic acid supplement with additional nutrients for kidney dialysis patients. Dialyvite 5000 is a small, round, purple, coated tablet, with debossed "H" on one side.

Each tablet contains:

Folic Acid.....5 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).....50 mg

Vitamin B12 (Methylcobalamin).....2 mg

Biotin.....300 mcg

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

Zinc (Zinc Citrate).....25 mg

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

Inactive ingredients:

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

INDICATIONS AND USAGE

Dialyvite 5000 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 10542-011-09

Dialyvite 5000

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

Hillestad Pharmaceuticals Inc.

Dialyvite Division

- 178 U.S. Hwy. 51 N. • Woodruff, WI 54568-9501
- www.dialyvite.net • Email: info@dialyvite.net
- Toll Free 866-358-9773



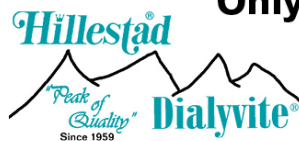
NDC 10542-011-09

Dialyvite® 5000

Multi-Vitamin Supplement
for Dialysis Patients

**Rx
Only**

**90
Tablets**



Supplement Facts

Serving Size: 1 Tablet

Amount Per Tablet	% Daily Value
Vitamin C (Ascorbic Acid)	100 mg 111%
Vitamin E (d-Alpha Tocopheryl Acid Succinate)	20.1 mg 134%
Thiamine (as Thiamine Mononitrate)	1.5 mg 125%
Riboflavin	1.7 mg 131%
Niacin (as Niacinamide)	20 mg 125%
Vitamin B6 (as Pyridoxine HCl)	50 mg 2941%
Folate	8333 mcg DFE 2083%
(5000 mcg Folic Acid)	
Vitamin B12 (as Methylcobalamin)	2 mg 83,333%
Biotin	300 mcg 1000%
Pantothenic Acid (as D-Calcium Pantothenate)	10 mg 200%
Zinc (as Zinc Citrate)	25 mg 227%
Selenium (Selenium Amino Acid Chelate)	70 mcg 127%

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

(Rev. 4)

Product #HP11

DIALYVITE 5000

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10542-011
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	100 mg

Thiamine Mononitrate (UNII: 8K0I04919X) (Thiamine Ion - UNII:4ABT0J945J)	Thiamine	1.5 mg
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	1.7 mg
Niacinamide (UNII: 25X5I8RD4) (Niacinamide - UNII:25X5I8RD4)	Niacinamide	20 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1B16Z)	Pyridoxine	50 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	5 mg
Cobalamin (UNII: 8406EY2OQA) (Cobalamin - UNII:8406EY2OQA)	Cobalamin	2 mg
Biotin (UNII: 6SO6U10H04) (Biotin - UNII:6SO6U10H04)	Biotin	300 ug
Calcium Pantothenate (UNII: 568ET80C3D) (Pantothenic Acid - UNII:19F5HK2737)	Pantothenic Acid	10 mg
Zinc Citrate (UNII: K72I3DEX9B) (Zinc Cation - UNII:13S1S8SF37)	Zinc Cation	25 mg
.alpha.-tocopherol succinate, d- (UNII: LU4B53JYVE) (.alpha.-tocopherol, d- - UNII:N9PR3490H9)	.alpha.-tocopherol, d-	30 [iU]
Selenocysteine (UNII: 0CH9049VIS) (Selenium - UNII:H6241UJ22B)	Selenium	70 ug

Inactive Ingredients

Ingredient Name	Strength
Microcrystalline Cellulose (UNII: OPIR32D61U)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Shellac (UNII: 46N107B71O)	
Starch, Corn (UNII: O8232NY3SJ)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Blueberry (UNII: 253RUG1X1A)	
Calcium Stearate (UNII: 776XM7047L)	

Product Characteristics

Color	purple	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10542-011-09	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2008	
2	NDC:10542-011-02	7 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		05/01/2008	

Labeler - Hillestad Pharmaceuticals USA (029291085)

Establishment

Name	Address	ID/FEI	Business Operations
Hillestad Pharmaceuticals USA		029291085	manufacture(10542-011) , label(10542-011)

Revised: 10/2019

Hillestad Pharmaceuticals USA