

**DIALYVITE - ascorbic acid, thiamine, riboflavin, niacinamide, pyridoxine, folic acid, cobalamin, biotin, pantothenic acid 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**

**DESCRIPTION**

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

**Each tablet contains:**

Folic Acid.....1 mg  
Vitamin C (Ascorbic Acid).....100 mg  
Thiamine (Thiamine Mononitrate).....1.5 mg  
Riboflavin.....1.7 mg  
Niacinamide.....20 mg  
Vitamin B6 (Pyridoxine HCl).....10 mg  
Vitamin B12 (Methylcobalamin).....6 mcg  
Biotin.....300 mcg  
Pantothenic Acid (Calcium Pantothenate).....10 mg

**Inactive ingredients:**

Microcrystalline Cellulose, Croscarmellose Sodium, Mono- and Diglycerides, Starch, Hypromellose, Polyethylene Glycol, Calcium Stearate, Carmine (color).

**INDICATIONS AND USAGE**

Dialyvite 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 as directed by your physician, orally.

## PRINCIPAL DISPLAY PANEL

NDC 10542-010-10

Dialyvite

Multivitamin Supplement for Dialysis Patients

100 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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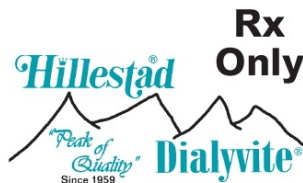


NDC 10542-010-10

# Dialyvite®

Multi-Vitamin Supplement  
for Dialysis Patients

100  
Tablets



Supplement Facts		
Serving Size: 1 Tablet		
Amount Per Tablet	% Daily Value	
Vitamin C (Ascorbic Acid) .....	100 mg	111%
Thiamine (as Thiamine Mononitrate) .....	1.5 mg	125%
Riboflavin .....	1.7 mg	131%
Niacin (as Niacinamide) .....	20 mg	125%
Vitamin B <sub>6</sub> (as Pyridoxine HCl) .....	10 mg	588%
Folate .....	1667 mcg DFE	417%
	(1000 mcg Folic Acid)	
Vitamin B <sub>12</sub> (as Methylcobalamin) .....	6 mcg	250%
Biotin .....	300 mcg	1000%
Pantothenic Acid (as D-Calcium Pantothenate) .....	10 mg	200%

Other Ingredients: Microcrystalline Cellulose, Croscarmellose Sodium, Mono- and Diglycerides, Starch, Hypromellose, Polyethylene Glycol, Calcium Stearate, Carmine (color).

(Rev. 6)

Product #HP10

## DIALYVITE

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

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:10542-010
<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	1 mg
<b>Cobalamin</b> (UNII: 8406EY2OQA) (Cobalamin - UNII:8406EY2OQA)	Cobalamin	6 ug
<b>Biotin</b> (UNII: 6SO6U10H04) (Biotin - UNII:6SO6U10H04)	Biotin	300 ug
<b>Calcium Pantothenate</b> (UNII: 568ET80C3D) (Pantothenic Acid - UNII:19F5HK2737)	Pantothenic Acid	10 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>Microcrystalline Cellulose</b> (UNII: OP1R32D61U)	
<b>Croscarmellose Sodium</b> (UNII: M28OL1HH48)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>Starch, Corn</b> (UNII: O8232NY3SJ)	
<b>Hypromellose, unspecified</b> (UNII: 3NXW29V3WO)	
<b>Polyethylene Glycol, unspecified</b> (UNII: 3WJQ0SDW1A)	
<b>Calcium Stearate</b> (UNII: 776XM7047L)	
<b>Cochineal</b> (UNII: TZ8Z31B35M)	

## Product Characteristics

<b>Color</b>	pink	<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
1	NDC:10542-010-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/1988	
2	NDC:10542-010-02	7 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/1988	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		08/01/1988	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Hillestad Pharmaceuticals USA		029291085	manufacture(10542-010) , pack(10542-010) , label(10542-010)

Revised: 10/2022

Hillestad Pharmaceuticals USA