

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.

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

Hillestad Pharmaceuticals Inc.
Dialyvite Division

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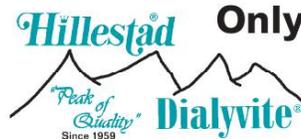


NDC 10542-010-10

Dialyvite®

Multi-Vitamin Supplement
for Dialysis Patients

100
Tablets



Supplement Facts		
Serving Size 1 Tablet		Servings Per Container 100
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 ₆ (as Pyridoxine HCl)	10 mg	588%
Folate	1667 mcg DFE	417%
	(1000 mcg Folic Acid)	
Vitamin B ₁₂ (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. 7)

Product #HP10

DIALYVITE

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10542-010
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: 25X51I8RD4) (Niacinamide - UNII:25X51I8RD4)	Niacinamide	20 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine	10 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1 mg
Cobalamin (UNII: 8406EY2OQA) (Cobalamin - UNII:8406EY2OQA)	Cobalamin	6 ug
Biotin (UNII: 6SO6U10H04) (Biotin - UNII:6SO6U10H04)	Biotin	300 ug
Calcium Pantothenate (UNII: 568ET80C3D) (Pantothenic Acid - UNII:19F5HK2737)	Pantothenic Acid	10 mg

Inactive Ingredients

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

Product Characteristics

Color	pink	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:10542-010-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/1988	01/31/2027
2	NDC:10542-010-02	7 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/1988	01/31/2027

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		08/01/1988	01/31/2027

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: 1/2026

Hillestad Pharmaceuticals USA