

DIALYVITE WITH ZINC - ascorbic acid, thiamine, riboflavin, niacinamide, pyridoxine, folic acid, cobalamin, biotin, pantothenic acid, zinc 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 with Zinc

DESCRIPTION

Dialyvite with Zinc is a prescription folic acid supplement with zinc and additional nutrients for kidney dialysis patients. Dialyvite with Zinc is a small, round, yellow, 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

Zinc (Zinc Citrate).....50 mg

Inactive ingredients:

Microcrystalline Cellulose, Croscarmellose Sodium, Mono-and Diglycerides, Pharmaceutical Glaze, Starch, Calcium Stearate.

INDICATIONS AND USAGE

Dialyvite with Zinc is a prescription folic acid supplement with Zinc and 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 10542-012-10

Dialyvite with Zinc

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 10542-012-10

Dialyvite[®]

with Zinc

Multi-Vitamin Supplement
for Dialysis Patients

Rx Only

100 Tablets

Other ingredients: Microcrystalline Cellulose, Croscarmellose Sodium, Mono- and Diglycerides, Pharmaceutical Glaze, Starch, Calcium Stearate.

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 B6 (as Pyridoxine HCl).....	10 mg 588%
Folate	1667 mcg DFE 417%
(1000 mcg Folic Acid)	
Vitamin B12 (as Methylcobalamin).....	6 mcg 250%
Biotin.....	300 mcg 1000%
Pantothenic Acid (as D-Calcium Pantothenate)	10 mg 200%
Zinc (as Zinc Citrate)	50 mg 455%

Other Ingredients: Microcrystalline Cellulose, Croscarmellose Sodium, Mono- and Diglycerides, Pharmaceutical Glaze, Starch, Calcium Stearate.

(Rev. 1)

Product #HP12

DIALYVITE WITH ZINC

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10542-012
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
Zinc Citrate (UNII: K72I3DEX9B) (Zinc Cation - UNII:13S1S8SF37)	Zinc Cation	50 mg

Inactive Ingredients

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

Product Characteristics

Color	yellow	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:10542-012-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2002	
2	NDC:10542-012-02	7 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2002	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		10/01/2002	

Labeler - Hillestad Pharmaceuticals USA (029291085)

Establishment

Name	Address	ID/FEI	Business Operations
Hillestad Pharmaceuticals USA		029291085	manufacture(10542-012) , label(10542-012)