DIALYVITE SUPREME D - ascorbic acid, cholecalciferol, alpha-tocopherol, 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 Supreme D

DESCRIPTION

Dialyvite Supreme D is a prescription folic acid supplement with additional nutrients for kidney dialysis patients. Dialyvite Supreme D is a small, round, light green, coated tablet, with debossed "H" on one side, and bisected on the other side.

Each tablet contains:

Folic Acid.....3 mg

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

Vitamin D (Cholecalciferol).....2000 IU

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

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, Starch, Silicon Dioxide, Calcium Stearate, Chlorophyllin (color).

INDICATIONS AND USAGE

Dialyvite Supreme D 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 or as directed by your physician, orally.

PRINCIPAL DISPLAY PANEL

NDC 10542-009-09

Dialyvite Supreme D

Multivitamin Supplement for Dialysis Patients

90 Tablets

DIALYVITE SUPREME D

ascorbic acid, cholecalciferol, alpha-tocopherol, 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:10542-009
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
Cholecalciferol (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	2000 [iU]
.alpha.-tocopherol succinate, d- (UNII: LU4B53JYVE) (.alpha.-tocopherol, d- - UNII:N9PR3490H9)	.alpha.-tocopherol, d-	30 [iU]
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 Hydrochloride	25 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	3 mg
Cobalamin (UNII: 8406EY2OQA) (Cobalamin - UNII:8406EY2OQA)	Cobalamin	1 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	15 mg
Selenocysteine (UNII: 0CH9049VIS) (Selenium - UNII:H6241UJ22B)	Selenium	70 ug

Inactive Ingredients

Ingredient Name	Strength
Microcrystalline Cellulose (UNII: OP1R32D61U)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Shellac (UNII: 46N107B71O)	
Starch, Corn (UNII: O8232NY3SJ)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Calcium Stearate (UNII: 776XM7047L)	
Sodium Copper Chlorophyllin (UNII: 1D276TYV9O)	

Product Characteristics

Color	green	**Score**	2 pieces
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10542-009-09	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/08/2010	
2	NDC:10542-009-02	7 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/08/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		09/08/2010	

Labeler - Hillestad Pharmaceuticals USA (029291085)

Establishment

Name	Address	ID/FEI	Business Operations
Hillestad Pharmaceuticals USA		029291085	manufacture(10542-009) , label(10542-009)

Revised: 10/2019 Hillestad Pharmaceuticals USA