

**DIALYVITE - ascorbic acid, thiamine, riboflavin, niacinamide, pyridoxine, folic acid, cobalamin, biotin, pantothenic acid tablet, coated**  
**Atlantic Biologicals Corps**

*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.

## HOW SUPPLIED

Product: 17856-0010

NDC: 17856-0010-4 1 TABLET, COATED in a DOSE PACK

## DIALYVITE (ASCORBIC ACID, THIAMINE, RIBOFLAVIN, NIACINAMIDE, PYRIDOXINE, FOLIC ACID, COBALAMIN, BIOTIN, PANTOTHENIC ACID) TABLET, COATED

**NDC 17856-0010-04**

**DIALYVITE**  
(Multi-Vitamin Supplement for Dialysis Patients)

**Rx Only**  
**UNIT DOSE**

**Drug Facts:**  
Serving Size: Single Dose Capsule  
Servings per container: 100  
See package insert for indications and dosage schedule.

**Other information:**  
Water-soluble B Vitamins and Vitamin C for use as a dietary supplement.

**KEEP DIALYVITE TABLETS AND ALL MEDICINES OUT OF THE REACH OF CHILDREN**

**Mfg by:** Hilestad Pharmaceuticals Inc.  
Dialyvit Division  
178 U.S. Hwy. 51 N.  
Woodruff, WI 54568-9501

**Repackaged by:** Unit Dose Solutions, Inc. Morrisville, NC 27560

**Distributed by:** Atlantic Biologicals Corp.  
20101 N.E. 16th Place  
Miami, FL 33179

**\*Retain box label and package insert for drug information.**

**Questions or Comments:**  
**Call 1-800-509-7592**

UDS Lot No: XXXXXX  
MFG Lot No: XXXXXX  
Exp. Date: XX/XX/XXXX

**17856001004**

**DIALYVITE**  
(MULTIVITAMIN SUPPLEMENT)

**UNIT-DOSE**  
**(100x1)**

DIALYVITE  
(MULTIVITAMIN SUPPLEMENT)  
700  
Exp. Date 04/20/2018  
UDS-#10, LOT# XXXXXX  
MFG- HILLESTAD  
MFG LOT# XXXXXX  
DISTR- ATLANTIC BIOLOGICALS  
**17856001004**

## 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:17856-0010(NDC:10542-010)
<b>Route of Administration</b>	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:17856-0010-4	100 in 1 CONTAINER	05/01/2017	
1		1 in 1 DOSE PACK ; Type 0: Not a Combination Product		

**Marketing Information**

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

**Labeler** - Atlantic Biologicals Corps (047437707)**Establishment**

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Revised: 5/2017

Atlantic Biologicals Corps