

COBALEFOL- vitamin capsule

V2 Pharma LLC

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](#).

Cobalefol

Supplement Facts

Cobalefol Capsules - Vitamins dispensed by prescription

Supplement Facts

Serving Size: 1 Capsule

Servings Per Bottle: 30

Ingredients	Amount Per Serving	%DV
Vitamin C (as Ascorbic Acid)	90 mg	100%
Vitamin D3 (as Cholecalciferol)	20 mcg	100%
Vitamin E (as d-Alpha Tocopheryl Succinate)	10.05 mg	67%
Thiamine (as Thiamine Mononitrate)	1.4 mg	116%
Riboflavin (as Riboflavin 5 Phosphate)	1.6 mg	123%
Niacin (as Niacinamide)	16.3 mg	101%
Vitamin B-6 (as Pyridoxine HCl)	2.5 mg	147%
Folate (from 1000 mcg Folic Acid)	1700 mcg DFE	425%
Vitamin B-12 (as Methylcobalamin)	10 mcg	416%

Other ingredients: Microcrystalline Cellulose (USP), Vegetable Capsule (cellulose, purified water)

Description:

Cobalefol is an orally administered vitamin formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced folate supplementation is needed. Cobalefol provides significant amounts of Vitamins B6, B12, C, D3, E, riboflavin, niacinamide, and thiamine mononitrate to supplement the diet.

Contraindications

Cobalefol is contraindicated in patients with a known hypersensitivity to any of the contained ingredients. Do not take this product if you are presently taking mineral oil, unless directed by a licensed medical practitioner.

Precaution

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B is deficient. Folic acid in doses above 1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress. Cobalefol should only be used under the direction and supervision of a licensed medical practitioner.

WARNINGS

KEEP COBALEFOL OUT OF THE REACH OF CHILDREN.

In case of accidental overdose, call a licensed medical practitioner or poison control center immediately.

For use under the supervision of a licensed medical practitioner.

Consult your physician prior to using Cobalefol if you are pregnant, nursing, taking medication, or have a medical condition.

Doseage and Administration

Suggested use is 1 capsule taken orally once daily or as prescribed by a licensed medical practitioner.

Storage and Handling

Store at room temperature. Avoid excessive heat, light, and moisture.

Statements

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

How Supplied

Cobalefol vitamin capsules are available in 30 count bottles. 72835-550-01

Manufactured for:
V2 Pharma, LLC
103 W Main Street
Hudson, MI 49247

Cobalefol Label

DOSAGE AND ADMINISTRATION:

Suggested use is 1 capsule taken orally once daily or as prescribed by a licensed medical practitioner.

WARNING: Consult your physician prior to using this product if you are pregnant, nursing, taking medication or have a medical condition.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Manufactured for: V2 Pharma, LLC
103 W Main Street Hudson, MI 49247
www.V2Pharma.com



72835-550-01

COBALEFOL

Dietary Supplement

Dispensed by Prescription

30
CAPSULES

Supplement Facts

Serving Size: 1 capsule
Servings per Container: 30

	Amount Per Serving	%DV
Vitamin C (as Ascorbic Acid)	90 mg	100%
Vitamin D3 (as Cholecalciferol)	20 mcg	100%
Vitamin E (as d-Alpha Tocopheryl Succinate)	10.05 mg	87%
Thiamine (as Thiamine Mononitrate)	1.4 mg	116%
Riboflavin (as Riboflavin 5 Phosphate)	1.6 mg	123%
Niacin (as Niacinamide)	16.3 mg	101%
Vitamin B-6 (as Pyridoxine HCl)	2.5 mg	147%
Folate (from 1000 mcg Folic Acid)	1700 mcg DFE	425%
Vitamin B-12 (as Methylcobalamin)	10 mcg	416%

† Daily value (dv) not established

Other ingredients: Microcrystalline Cellulose (USP) Vegetable Capsule (cellulose, purified water).

No artificial colors, artificial flavors, milk or milk derivatives, or sodium added.

STORAGE: Store at room temperature. Avoid excessive heat, light and moisture.

Made in a GMP Compliant Facility in the U.S.
Product Number:

COBALEFOL

vitamin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72835-550
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	90 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	20 ug
.ALPHA.-TOCOPHEROL SUCCINATE, D- (UNII: LU4B53JYVE) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL SUCCINATE, D-	10.5 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABTOJ945J)	THIAMINE MONONITRATE	1.4 mg
RIBOFLAVIN 5'-PHOSPHATE (UNII: 7N464URE7E) (FLAVIN MONONUCLEOTIDE - UNII:7N464URE7E)	RIBOFLAVIN 5'-PHOSPHATE	1.6 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	16.3 mg
PYRIDOXINE HCL (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	2.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1700 ug
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	10 ug

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Product Characteristics

Color	white	Score	no score
Shape	capsule	Size	16mm

Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72835-550-01	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2025	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
unapproved drug other			05/16/2025	

Labeler - V2 Pharma LLC (102457346)

Establishment			
Name	Address	ID/FEI	Business Operations
V2 Pharma LLC		102457346	label(72835-550) , manufacture(72835-550)