

VP-VITE RX- ascorbic acid, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, biotin, and calcium pantothenate tablet
Virtus Pharmaceuticals

VP-Vite Rx

69543-356-10

Rx

Prescription Folic Acid-Containing Dietary Supplement

DESCRIPTION

VP-Vite Rx is an orally administered prescription dietary supplement and should be administered under the supervision of a licensed medical practitioner.

Supplement Facts		
Serving Size: 1 Tablet		
	Amount Per Serving	% Daily Value
Vitamin C (ascorbic acid)	60 mg	100%
Vitamin B₁ (thiamine mononitrate)	1.5 mg	100%
Vitamin B₂ (riboflavin)	1.7 mg	100%
Niacinamide (vitamin B ₃)	20 mg	100%
Vitamin B₆ (pyridoxine HCl)	10 mg	500%
Folic Acid	1 mg	250%
Vitamin B₁₂ (cyanocobalamin)	6 mcg	100%
Biotin	300 mcg	100%
Pantothenic Acid (calcium pantothenate)	10 mg	100%

Other Ingredients: Dicalcium Phosphate, Microcrystalline Cellulose, Stearic Acid, Magnesium Stearate, Croscarmellose Sodium, Silica, Hypromellose, Titanium Dioxide, and FD&C Yellow #5.

Contains FD&C Yellow #5

INDICATIONS AND USAGE

VP-Vite Rx is indicated for the supplemental requirements of persons with nutritional deficiencies or those who are in need of nutritional supplementation.

CONTRAINDICATIONS

This product is contraindicated in persons with a known hypersensitivity to any of the ingredients.

PRECAUTIONS

High levels of folic acid may, especially in older adults, hide signs of vitamin B-12 deficiency (such as pernicious anemia, a condition that can cause nerve damage).

PATIENT INFORMATION

VP-Vite Rx is a prescription vitamin for use only under the direction and supervision of a licensed physician.

DRUG INTERACTIONS

Pyridoxine hydrochloride should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxine hydrochloride. However, pyridoxine hydrochloride may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa.

Drugs which may interact with folate include:

- Antiepileptic drugs (AED): The AED class including, but not limited to, phenytoin, carbamazepine, primidone, valproic acid, phenobarbital and lamotrigine have been shown to impair folate absorption and increase the metabolism of circulating folate. Additionally, concurrent use of folic acid has been associated with enhanced phenytoin metabolism, lowering the levels of this AED in the blood and allowing breakthrough seizures to occur.
- Capecitabine: Folinic acid (5-formyltetrahydrofolate) may increase the toxicity of Capecitabine.
- Cholestyramine: Reduces folic acid absorption and reduces serum folate levels.
- Colestipol: Reduces folic acid absorption and reduces serum folate levels.
- Cycloserine: Reduces folic acid absorption and reduces serum folate levels.
- Dihydrofolate Reductase Inhibitors (DHFRIs): DHFRIs including aminopterin, methotrexate, pyrimethamine, triamterene, and trimethoprim, block the conversion of folic acid to its active forms, and lower plasma and red blood cell folate levels.
- Fluoxetine: Fluoxetine exerts a noncompetitive inhibition of 5-methyltetrahydrofolate active transport in the intestine.
- Isotretinoin: Reduced folate levels have occurred in some patients taking isotretinoin.
- Nonsteroidal Anti-inflammatory Drugs (NSAIDs): NSAIDs, including ibuprofen, naproxen, indomethacin and sulindac, have been shown to inhibit some folate-dependent enzymes in laboratory experiments.
- Oral Contraceptives: Serum folate levels may be depressed by oral contraceptive therapy.
- Methylprednisolone: Reduced serum folate levels have been noted after treatment with methylprednisolone.
- Pancreatic Enzymes: Reduced folate levels have occurred in some patients taking pancreatic extracts.
- Pentamidine: Reduced folate levels have been seen with prolonged intravenous pentamidine treatment.
- Smoking and alcohol: Reduced serum folate levels have been noted.
- Sulfasalazine: Inhibits the absorption and metabolism of folic acid.
- Metformin treatment in patients with type 2 diabetes decreases serum folate.
- Warfarin can produce significant impairment in folate status after a 6-month therapy.

SIDE EFFECTS

Allergic sensitization has been reported following oral administration of folic acid. Paresthesia, somnolence, nausea and headaches have been reported with pyridoxine hydrochloride. Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body have been associated with cyanocobalamin.

DIRECTIONS FOR USE

1 tablet daily with or without food or as prescribed by a licensed medical practitioner.

HOW SUPPLIED

VP-Vite Rx Supplied as round, yellow tablet imprinted with "V356" dispensed in 100 count bottles.

69543-356-10

STORAGE

Store at 20° to 25°C (68° to 77°F), excursions permitted to 15° to 30°C (59° to 86°F) Protect from light and moisture. Dispense in a tight, light-resistant container. Notice: Contact with moisture may produce surface discoloration or erosion.

Call your licensed medical practitioner about side effects. You may report side effects by calling Virtus at 1-888-848-3593 or FDA at 1-800-FDA-1088.

KEEP OUT OF REACH OF CHILDREN

Rx

Manufactured for:

Virtus Pharmaceuticals, LLC

Tampa, FL 33619

1-888-848-3593

Rev. 06/15

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

VIRTUS

PHARMACEUTICALS

69543-356-10

VP-Vite Rx

**Prescription Folic Acid-Containing
Dietary Supplement**

R_x

100 Tablets

Made in the USA



69543-356-10

VP-Vite Rx

Prescription Folic Acid-Containing Dietary Supplement

Rx

100 Tablets

Made in the USA

Supplement Facts

Serving Size 1 Tablet

	Amount Per Serving	% Daily Value
Vitamin C (ascorbic acid)	60 mg	100%
Vitamin B1 (thiamine mononitrate)	1.5 mg	100%
Vitamin B2 (riboflavin)	1.7 mg	100%
Niacinamide (vitamin B3)	20 mg	100%
Vitamin B6 (pyridoxine HCl)	10 mg	500%
Folic Acid	1 mg	250%
Vitamin B12 (cyanocobalamin)	6 mcg	100%
Biotin	300 mcg	100%
Pantothenic Acid (calcium pantothenate)	10 mg	100%

Other Ingredients: Dicalcium Phosphate, Microcrystalline Cellulose, Stearic Acid, Magnesium Stearate, Croscarmellose Sodium, Silica, Hypromellose, Titanium Dioxide, and FD&C Yellow #5. Contains FD&C Yellow #5

DESCRIPTION: VP-Vite Rx is an orally administered prescription dietary supplement and should be administered under the supervision of a licensed medical practitioner.

DIRECTIONS FOR USE: 1 tablet daily with or without food or as prescribed by a licensed medical practitioner.

CAUTION: High levels of folic acid may hide signs of B-12 deficiency, such as pernicious anemia. See prescribing information.

PRECAUTIONS, CONTRAINDICATIONS, SIDE EFFECTS: See Prescribing Information.

KEEP OUT OF REACH OF CHILDREN.

STORAGE: Store at controlled room temperature 20° to 25°C (68° to 77°F); excursions permitted 15° to 30°C (68° to 86°F). Protect from light and moisture. Dispense in a tight, light-resistant container. Notice: Contact with moisture may produce surface discoloration or erosion.

Call your licensed medical practitioner about side effects. You may report side effects by calling Virtus at 1-888-848-3593 or FDA at 1-800-FDA-1088.

Manufactured for:
Virtus Pharmaceuticals, LLC
Tampa, FL 33619
1-888-848-3593
Rev. 06/2015



Lot:
Exp:

VP-VITE RX

ascorbic acid, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, biotin, and calcium pantothenate tablet

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69543-356
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 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
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	6 ug
Biotin (UNII: 6SO6U10H04) (Biotin - UNII:6SO6U10H04)	Biotin	300 ug
Calcium Pantothenate (UNII: 568ET80C3D) (Pantothenic Acid - UNII:19F5HK2737, Calcium Cation - UNII:2M83C4R6ZB)	Pantothenic Acid	10 mg

Inactive Ingredients

Ingredient Name	Strength
Calcium Phosphate, Dibasic, Anhydrous (UNII: L11K75P92J)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Magnesium Stearate (UNII: 70097M6I30)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Hypromelloses (UNII: 3NXW29V3WO)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

