

DESCRIPTION: VP-ZEL Tabs is an orally administered prescription dietary supplement specifically formulated for the dietary management of patients with unique nutritional needs requiring increased folate levels and nutritional supplementation.

VP-ZEL Tabs should be administered under the supervision of a licensed medical practitioner.

Each coated, purple colored, oval-shaped tablet contains the following dietary ingredients:

Supplement Facts		
Serving Size: 1 Pill	Servings Per Container: 60	
	Amount Per Serving	% Daily Value
Nicotinamide (Vitamin B ₃)	600 mg	**
Azelaic Acid*	5 mg	**
Zinc (Zinc Oxide)	10 mg	**
Pyridoxine (Vitamin B ₆)	5 mg	**
Copper (Cupric Oxide)	1.5 mg	**
Folic Acid	500 mcg	**

*Azelaic acid is an organic compound with the formula (CH₃)₂(CO₂H)₂ (or also as C₈H₁₄O₄), and has CAS number 123-99-9. It is in the dicarboxylic acid (saturated) group, and occurs naturally in wheat, rye, and barley.

**Daily Values not established for patients with unique nutritional needs who are in need of supplementation as directed by a licensed medical practitioner.



NDC 76439-221-60

VP-ZEL Tabs

TABLETS

Prescription Dietary Supplement

Rx

60 Tablets

Made in the USA

DOSAGE AND ADMINISTRATION: Usual adult dose is one or two tablets taken once or twice a day with or without food or as directed by a licensed medical practitioner.

STORAGE: Store at Controlled Room Temperature 15°-30° C (59°-86° F). [See USP]. Protect from light and moisture. Dispense in a tight, light-resistant container.

KEEP THIS OUT OF REACH OF CHILDREN.

If you are pregnant or nursing a baby, please ask a health professional.

This is not an Orange Book product.

Call your licensed medical practitioner about side effects.

You may report side effects by calling 813-283-1344.

NDC# 76439-221-60

*See insert for more information about National Drug Codes (NDC).

Manufactured for:

Virtus Pharmaceuticals, LLC

Tampa, FL 33619

MADE IN USA

Rev. 09/12



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**DV values not established for patients with unique nutritional needs who are in need of supplementation as directed by a licensed medical practitioner.

Other ingredients: Microcrystalline cellulose, dicalcium phosphate, croscarmellose sodium, stearic acid, magnesium stearate, silica, and film coat (polyvinyl alcohol, polyethylene glycol, titanium dioxide, talc, FD&C blue #1 lake, and FD&C red #3).

FOLATE REGULATION: The term "folate" are B vitamins that include folic acid and any forms of active pteroylglutamates regardless of the reduction state of the molecule. Foliates, or vitamin B₉, are primarily hydrolyzed in the intestinal jejunum and the liver to the active circulating form of folate, L-methylfolate, with an intermediate stable form, 5,10-methylenetetrahydrofolate.

Individuals with genetic polymorphisms for the genes coding methylenetetrahydrofolate reductase (MTHFR) may not be capable of utilizing or metabolizing folic acid adequately for the vitamin B₁₂ dependent methylation cycle.

Folic acid, including reduced forms* such as folic acid, may obscure pernicious anemia above 0.1 mg doses, and must be administered under the supervision of a licensed medical practitioner.

The 1971, 1972, 1973, 1980, 1984, 2000, and 2010 Federal Register Notices addressed this concern while establishing that increased folate was proper therapy in megaloblastic anemias - specifically where homocysteine levels were elevated or risk of neural tube defects (NTDs) was at issue. The Federal Register Notice of August 2, 1973 (38 FR 20750) specifically states that:

Dietary supplement preparations are available without a prescription (21 CFR 121.1134). Levels higher than dietary supplement amounts are available only with a prescription.

*It is not known whether or not L-methylfolate can obscure pernicious anemia above 0.1 mg doses, so caution is advised also with this form of folate.

Folic acid - including reduced forms, may be added to medical foods as defined in section 5(b) (3) of the Orphan Drug Act (21 USC 360ee(b)(3)), or to food (21 CFR 172.345).

INDICATIONS AND USAGE: VP-ZEL Tabs is indicated for the distinct nutritional requirements of patients in need of dietary supplementation as determined by a licensed medical practitioner. VP-ZEL Tabs should be administered under the supervision of a licensed medical practitioner.

CONTRAINDICATIONS: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

WARNINGS: Caution is recommended in patients with a history of bipolar illness.

PRECAUTIONS: General: Folate, when administered as a single agent in doses about 0.1 mg daily, may obscure the detection of vitamin B₁₂ deficiency (specifically, the administration of folic acid may reverse the hematological manifestations of B₁₂ deficiency, including pernicious anemia, while not addressing the neurological manifestations). Folate therapy alone is inadequate for treatment of a vitamin B₁₂ deficiency.

PATIENT INFORMATION: VP-ZEL Tabs is a prescription dietary supplement to be used only under licensed medical supervision.

DRUG INTERACTIONS: Drugs which may interact with folate include:

- Antiepileptic drugs (AED): The AED class including, but not limited to, phenytoin, carbamazepine, primidone, valproic acid, fosphenytoin, valproate, 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 level of the AED in the blood and allowing breakthrough seizures to occur. Caution should be used when prescribing this product among patients who are receiving treatment with phenytoin and other anticonvulsants.
- Capecitabine: Folic 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 block the conversion of folic acid to its active forms, and lower plasma and red blood cell folate levels. DHFRIs include aminopterin, methotrexate, pyrimethamine, triamterene, and trimethoprim.
- Fluoxetine: Fluoxetine exerts a noncompetitive inhibition of the 5-methyltetrahydrofolate active transport in the intestine.
- Isotretinoin: Reduced folate levels have occurred in some patients taking isotretinoin.
- L-dopa, triamterene, colchicine, and trimethoprim may decrease plasma folate levels.
- Nonsteroidal Anti-inflammatory Drugs (NSAIDs): NSAIDs have been shown to inhibit some folate dependent enzymes in laboratory experiments.
- NSAIDs include ibuprofen, naproxen, indomethacin and sulindac.
- 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, such as pancreatin and pancrelipase.
- Pentamidine: Reduced folate levels have been seen with prolonged intravenous pentamidine.
- Pyrimethamine: High levels of folic acid may result in decreased serum levels of pyrimethamine.
- 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.

Drugs which may interact with nicotinamide:

- The clearance of primidone and carbamazepine may be reduced with the concomitant use of nicotinamide.

Drugs which may interact with zinc oxide:

- The absorption of quinolones or tetracycline may be decreased with the concomitant use of zinc.

Drugs which may interact with cupric oxide:

- Concomitant use of penicillamine and copper can cause decreased absorption of both substances.

PREGNANCY AND NURSING MOTHERS: VP-ZEL Tabs is not intended for use as a prenatal/ postnatal multivitamin for lactating and nonlactating mothers. Talk with your medical practitioner before using if pregnant or lactating.

ADVERSE REACTIONS: Allergic sensitization has been reported following both oral and parental administration of folic acid, and may possibly occur with other forms of folate.

DOSAGE AND ADMINISTRATION: Usual adult dose is one or two tablets taken once or twice a day with or without food or as directed by a licensed medical practitioner.

HOW SUPPLIED: VP-ZEL Tabs tablets are coated, purple colored, oval-shaped tablets debossed on one side with "V221", and are supplied in bottles of 60 tablets.

STORAGE: Store at Controlled Room Temperature 15°-30° C (59°-86° F). [See USP]. Protect from light and moisture. Dispense in a tight, light-resistant container.

KEEP THIS OUT OF REACH OF CHILDREN.

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. Call your licensed medical practitioner about side effects. You may report side effects by calling 813-283-1344.

NDC# 76439-221-60

*These products are dietary supplements that - due to increased folate levels (AUG 3 1973 FR 20750), require an Rx on the label because of increased risk associated with masking of B₁₂ deficiency. As such this product requires licensed medical supervision, an Rx status, and a national drug code (NDC) as required by pedigree reporting requirements.

VP-ZEL Tabs
Tablets
60ct Bottle
Rx
Prescription Dietary Supplement

Manufactured for:

Virtus Pharmaceuticals

Tampa, FL 33619

MADE IN USA



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