DOSAGE AND ADMINISTRATION: Usual adult dose is one tablet daily, or as directed by a physician or health-care provider. For dialysis patients, Folbee Plus® CZ should be taken after dialysis treatment.

If pregnant, or planning to become pregnant or are currently breast-feeding please contact your physician, or health-care provider before using or continuing use.

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.

PATIENT INFORMATION: Folbee Plus® CZ Tablets are for use only under the direction and supervision of a licensed physician or health-care provider.

WARNING: KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature. Protect from light and moisture. Dispense in a tight, light-resistant container with a child-resistant closure as defined in the USP/NF.

All substitutions using this product shall be pursuant to state statutes as applicable.
This is not an Orange Book product.

To report a serious adverse event contact: 1-800-367-3395.

Manufactured by:
Contract Pharmacal Corp.
Hauppauge, NY 11788

Distributed by:
Breckenridge Pharmaceutical, Inc.
Berlin, CT 06037

7679-05-20

3 51991 52890 6

51991-528-90

Folbee Plus® CZ

Sugar, Lactose, Yeast & Gluten Free

Do not use this product if the inner safety seal under the cap is torn, broken or missing.

Medical Food 90 Tablets

breckenridge | A Towa Company

Each Folbee Plus® CZ Tablet contains:

Vitamin C (as Ascorbic Acid)	60 mg
Vitamin B_1 (as Thiamine Mononitrate)	1.5 mg
Vitamin B_2 (as Riboflavin)	1.5 mg
Niacin (as Niacinamide)	20 mg
Vitamin B_6 (as Pyridoxine HCl)	50 mg
Folic Acid (Folacin)	5 mg
Vitamin B_{12} (as Cyanocobalamin)	2 mg
D-Biotin	300 mcg
Pantothenic Acid (as Calcium Pantothenate)	10 mg
Zinc (as Zinc Oxide)	25 mg
Copper (as Copper Gluconate)	1.5 mg

Other ingredients: Dicalcium Phosphate, Microcrystalline Cellulose, Hypromellose, Croscarmellose Sodium, Stearic Acid, Titanium Dioxide, Crospovidone, Magnesium Silicate, Sodium Lauryl Sulfate, Soy Polysaccharide, Magnesium Stearate, Silica, FD&C Yellow No. 5 Lake* and FD&C Yellow No. 6 Lake**.

* Contains FD&C Yellow No. 5 Lake (Tartrazine) as a color additive (see **PRECAUTIONS**).

** Contains FD&C Yellow No. 6 Lake as a color additive.

Allergen: Contains Soy.

HOW SUPPLIED

Folbee Plus® CZ Tablets are available as an oval-shaped, beige coated tablet, debossed "B 528" in bottles of 90 tablets, 51991-528-90.

PEEL HERE FOR MORE INFORMATION

Lot # & Exp. Date:

INDICATIONS AND USAGE For the dietary management of individuals with distinct nutritional needs for hyperhomocysteinemia; with particular emphasis for those individuals diagnosed with chronic kidney disease[1,2] (CKD), end stage renal disease[3] (ESRD), or dialysis[4].

Folbee Plus® CZ is labeled as a medical food intended for use under active and ongoing medical supervision requiring medical care on a recurring basis for, among other things, instructions on the use of the medical food.

MEDICAL FOODS: Medical foods are intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of a normal diet alone. Although a medical-food product is intended for use under the active and ongoing medical supervision, FDA does not require a prescription.

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.

CONTRAINDICATIONS: Known hypersensitivity to any of the components in the product is a contraindication.

PRECAUTIONS: This product contains FD&C Yellow No. 5 Lake (Tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 Lake (Tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

Folacin (folic acid) when administered as a single agent in doses above 0.1 mg daily, may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. The 2 mg of cyanocobalamin contained in Folbee Plus® CZ Tablets has been shown to provide an adequate amount of cyanocobalamin to address this precaution. A safe upper limit of 100 mg per day has been established for the unsupervised medical use of pyridoxine. Consider all sources of pyridoxine supplementation when prescribing Folbee Plus® CZ Tablets.

If pregnant, or planning to become pregnant or are currently breast-feeding please contact your physician, or health-care provider before using or continuing use.

WARNINGS: Folic Acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B_{12} is deficient.

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

DRUG INTERACTIONS: Pyridoxine should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxine. However, pyridoxine may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa. Concurrent use of phenytoin and folacin (folic acid) may result in decreased phenytoin effectiveness.

REFERENCES

1. Ninomiya T, Kiyohara Y, Kubo M, Tanizaki Y, Tanaka K, Okubo K, Nakamura H, Hata J, Oishi Y, Kato I, Hirakata H, and Iida M: Hyperhomocysteinemia and the Development of Chronic Kidney Disease in a General Population: The Hisayama Study. American Journal of Kidney Diseases 2004; Vol 44, NO 3:437-445.
2. Frances ME, Eggers PW, Hostetter TH, and Briggs JP: Association between serum homocysteine and markers of impaired kidney function in adults in the United States. Kidney International 2004; Vol 66:303-312
3. Stanford JL, Malina H, Phillips J, Kohlman-Trigoboff D, Moore J, and Smith BM: Oral folate reduces plasma homocysteine levels in hemodialysis patients with cardiovascular disease. Cardiovascular Surgery 2000; Vol 8, NO 7:567-571.
4. Mallamaci F, Zoccali C, Tripepi G, Fermo I, Benedetto FA, Catalioti A, Bellanuova I, Malatino LS, and Soldarini A: Hyperhomocysteinemia predicts cardiovascular outcomes in hemodialysis patients. Kidney International 2002; 61:1609-614.
5. Kuriminski AM, Del Giacco EJ, Allen RH, et al: Effective Treatment Of Cobalamin Deficiency With Oral Cobalamin. Blood 1998; 92:1191-1198