





Folbee Plus[®] & Folbee Plus[®] CZ

ATTENTION HEALTHCARE PROVIDER:
If your patients are looking
for a cost-effective combination
of Folacin (Folic Acid) with
Multiple Vitamins, then consider
Folbee Plus[®] and Folbee Plus[®] CZ.



PRODUCT NUMBER	BRECKENRIDGE PRODUCT	EACH TABLET CONTAINS	DETAILED DESCRIPTION	SIZE
51991-082-90	Folbee Plus [®] Tablets	Folic Acid (Folacin)5 mg Vitamin B ₁₂ (as Cyanocobalamin) 1 mg Vitamin B ₁ (as Thiamine HCl)1.5 mg Vitamin B ₂ (as Riboflavin)1.5 mg Vitamin B ₆ (as Pyridoxine HCl)50 mg Vitamin B ₃ (as Niacinamide)20 mg Vitamin C (as Ascorbic Acid)60 mg Pantothenic Acid (as Calcium Pantothenate)10 mg D-Biotin300 mcg	Yellow, film-coated capsule-shaped tablet, debossed B-082 	90
51991-528-90	Folbee Plus [®] CZ Tablets	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-Biotin300 mcg Pantothenic Acid (as Calcium Pantothenate)10 mg Zinc (as Zinc Oxide)25 mg Copper (as Copper Gluconate)1.5 mg	Oval-shaped, beige coated tablet, debossed B-528 	90

See Product Information on back for more information regarding Medical Foods.

Folbee Plus[®] and Folbee Plus[®] CZ tablets are labeled as medical foods intended for use under active and ongoing medical supervision. 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.

For more information on these products or to take advantage of our sampling program, give us a call or visit us at www.bpirx.com.



**Breckenridge
Pharmaceutical, Inc.**
Boca Raton, FL 33487
www.bpirx.com

**Phone (800) 367-3395
Fax (866) 372-7479
email: info@bpirx.com**

Folbee Plus® Tablets Medical Food

Each Folbee Plus® contains:

Folic Acid (as Folicin)	5 mg
Vitamin B ₁₂ (as Cyanocobalamin)	1 mg
Vitamin B ₁ (as Thiamine HCl)	1.5 mg
Vitamin B ₂ (as Riboflavin)	1.5 mg
Vitamin B ₆ (as Pyridoxine HCl)	50 mg
Vitamin B ₃ (as Niacinamide)	20 mg
Vitamin C (as Ascorbic Acid)	60 mg
Pantothenic Acid (as Calcium Pantothenate) ..	10 mg
D-Biotin	300 mcg

Folbee Plus® Tablets do not contain sugar or lactose.

Other ingredients:

Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Hypromellose, Stearic Acid, Titanium Dioxide, Sodium Lauryl Sulfate, Magnesium Silicate, Triacetin, Magnesium Stearate and Mineral Oil.

INDICATIONS AND USAGE:

For the dietary management of individuals with distinct nutritional needs under a physician or health-care provider's supervision for end stage renal failure, dialysis, hyperhomocysteinemia or inadequate dietary vitamin intake.

Folbee Plus® Tablets are 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.

This product is recommended for use under the supervision of a physician, or health-care provider.

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.

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 (as Folicin)	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.

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 disease³ (ESRD), or dialysis⁴.

Folbee Plus® 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 (tartrazine) which may

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.

WARNINGS: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B₁₂ is deficient.

Do not exceed recommended dosage.

PRECAUTIONS:

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 1 mg of cyanocobalamin contained in Folbee Plus® 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® 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.

ADVERSE REACTIONS:

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. Paresthesia and somnolence have been reported with pyridoxine HCl. Mild transient diarrhea, polycythemia vera, peripheral vascular thrombosis, itching transitory exanthema and feeling of swelling of entire body has been associated with cyanocobalamin.

DRUG INTERACTIONS:

Pyridoxine supplements 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 folicin (folic acid) may result in decreased phenytoin effectiveness.

Folbee Plus® CZ Tablets Medical Food

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

Folicin (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 has been shown to provide an adequate amount of cyanocobalamin to address this precaution⁵. 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.

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 B₁₂ is deficient.

ADVERSE REACTIONS:

Allergic sensitization has been reported following both oral and parenteral administration of Folicin (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 folicin (folic acid) may result in decreased phenytoin effectiveness.

PATIENT INFORMATION:

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

DOSE 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.

HOW SUPPLIED:

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

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.

PATIENT INFORMATION:

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

DOSE AND ADMINISTRATION:

Usual adult dosage is one tablet daily, between meals, or as directed by a physician or health-care provider. For dialysis patients, Folbee Plus® should be taken daily. On dialysis days, Folbee Plus® should be taken after dialysis treatment.

HOW SUPPLIED:

Folbee Plus® Tablets are available as a yellow, film-coated, capsule shaped tablet, debossed B-082 in bottles of 90 tablets, 51991-082-90.

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 child-resistant closure as defined in the USP/NF.

Manufactured by: Contract Pharmacal Corp.
Hauppauge, NY 11788 USA

Distributed by: Breckenridge Pharmaceutical, Inc.
Boca Raton, FL 33487

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.

Some or all of the following patents may apply:

U.S. Patent No. 4,940,658;

U.S. Patent No. 5,563,126;

U.S. Patent No. 5,795,873;

U.S. Patent No. 6,207,651;

U.S. Patent No. 6,297,224;

U.S. Patent No. 6,528,496;

and other pending patent applications.

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

Rev. 05/2011

Dispense in a tight, light-resistant container with a child-resistant closure as defined in the USP/NF.

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REFERENCES:

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 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, Molina 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.
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 5. Kuzminski AM, Del Giacco EJ, Allen RH, et al: Effective Treatment Of Cobalamin Deficiency With Oral Cobalamin. Blood 1998; 92:1191-1198
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