DOSAGE 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® Tablets 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.

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.

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.

Rev. 01/13

Manufactured by:
Contract Pharmacal Corp.
Hauppauge, NY 11788

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

N 3 51991 08290 3

Breckenridge Pharmaceutical, Inc.

51991-082-90

Sugar and Lactose Free

Folbee Plus®

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

Medical Food

90 Tablets

Each Folbee Plus® Tablet contains:

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-Biotin	300 mcg

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

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

Lot#/Exp.:

PEEL HERE FOR MORE INFORMATION

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.

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 B_{12} 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 vara, 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 preperation containing both carbidopa and levodopa. Concurrent use of phenytoin and folacin (folic acid) may result in decreased phenytoin effectiveness.

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