

Folbee Plus® Tablets

(Rx Only)

Description:

Each Folbee Plus® film-coated yellow tablet contains:

Folic Acid	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.

Inactive Ingredients:

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

Indication and Usage:

Folbee Plus® Tablets are indicated for the distinctive nutritional requirements of patients under a physician's treatment for end stage renal failure, dialysis, hyperhomocysteinemia, or inadequate dietary vitamin intake.

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.

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.

Contraindications:

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

Drug Interactions:

Pyridoxine supplements should not be given to patients receiving levodopa, because the action of the latter drug is antagonized by pyridoxine. However, this vitamin may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa. Concurrent use of phenytoin and folic acid may result in decreased phenytoin effectiveness.

Patient Information:

Folbee Plus® Tablets are a medical food, for use only under the direction and supervision of a licensed physician.

Dosage and Administration:

Usual adult dose is one tablet daily between meals as directed by physician. For dialysis patients, Folbee Plus® should be taken daily. On dialysis days, Folbee Plus® should be taken after treatment.

How Supplied:

Folbee Plus® Tablets are available as capsule-shaped, film-coated, yellow tablets. Debossed with B 082. Supplied in bottles of 90 tablets, NDC# 51991-082-90.

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

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.

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

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.

Rx ONLY

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

Rev. 08/08 MG #19452