



Folbic™ and Folbee® Tablets



ATTENTION HEALTHCARE PROVIDER:

If your patients are looking for a cost-effective combination of Folacin (Folic Acid) with B6 & B12, then consider **Folbic™** and **Folbee®**.



PRODUCT NUMBER	BRECKENRIDGE PRODUCT	EACH TABLET CONTAINS	DETAILED DESCRIPTION	SIZE
51991-384-90	Folbic™ Tablets	Vitamin B ₆ (as Pyridoxine HCl)25 mg Folacin (Folic Acid)2.5 mg Vitamin B ₁₂ (as Cyanocobalamin) ...2 mg	Oval, Rose-Colored Tablet, Debossed B 384 	90
51991-084-90	Folbee® Tablets	Vitamin B ₆ (as Pyridoxine HCl)25 mg Folacin (Folic Acid)2.5 mg Vitamin B ₁₂ (as Cyanocobalamin) ...1 mg	Oval, Natural Orangish Colored Tablet, Debossed B 084 	90

IMPORTANT FACTS ABOUT FOLBIC™ AND FOLBEE®

Folbee® and Folbic™ 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.

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

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

Folbic™ Tablets Medical Food

Each Folbic™ Tablet contains:

Vitamin B₆ (as Pyridoxine HCl) 25 mg
Folacin (Folic Acid) 2.5 mg
Vitamin B₁₂ (as Cyanocobalamin) 2 mg

Other Ingredients:

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

*Contains Carmine as a color additive.

INDICATIONS AND USAGE:

For the dietary management of individuals with distinct nutritional needs under a physician or health-care provider's supervision for hyperhomocysteinemia; with particular emphasis for individuals with or at risk for atherosclerotic vascular disease in the coronary¹, peripheral², or cerebral³ vessels, or vitamin B₁₂ deficiency⁴. Folbic 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.

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.

PRECAUTIONS:

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 mgs of cyanocobalamin contained in Folbic™ Tablets has been shown to provide an adequate amount of cyanocobalamin to address this precaution⁵. Unmetabolized folic acid has been shown in one study of 105 postmenopausal women (50-75 yrs) to have the potential to reduce natural killer cells' cytotoxicity, which may result in an impaired immune response⁶.

Cyanocobalamin should not be used in those with Leber's optic atrophy. Decreased levels of B₁₂ have been associated with reduced ability to detoxify the cyanide in exposed individuals and cyanocobalamin may increase the risk of irreversible neurological damage from optic atrophy in those affected with the disorder. Hydroxocobalamin can aid in the detoxification of cyanide. This form of B₁₂ is an acceptable form for B₁₂ supplementation in those with this disorder.

Pregnant women and nursing mothers should only use 12 microgram doses of B₁₂ (cyanocobalamin) from nutritional supplements. Doses higher than this should only be recommended by your physician. Administration of doses of vitamin B₁₂ greater than 10 micrograms daily may produce a hematological response in those with anemia secondary to folate deficiency.

If pregnant, or planning to become pregnant or are currently breastfeeding 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 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.

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 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.

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

DOSAGE AND ADMINISTRATION: Usual adult dosage is one to two tablets daily, or as directed by a physician or health-care provider.

HOW SUPPLIED: Folbic™ Tablets are available as an oval, rose colored tablet, debossed B 384. Supplied in bottles of 90 Tablets, 51991-384-90.

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.

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

Medical Food

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

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

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

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.

References:

¹Eikelboom JW, Lonn Eva, Genest Jr Jaques, Hankey Graeme, Yusuf Salim: Homocysteine and Cardiovascular Disease: A Critical Review of the Epidemiologic Evidence. Ann Intern Med. 1999; 131:363-375.

²The Homocysteine Studies Collaboration: Homocysteine and Risk of Ischemic Heart Disease and Stroke. JAMA 2002; Vol 288, No. 16:2015-2002.

³Refsum Helga, Smith A. David, Ueland Per M, Nexo Ebba, Clarke Robert, McPartlin Joseph, Johnston Carole, Engbaek Frode, Schneede Jorn, McPartlin Catherine, and Scott John M.: Facts and Recommendations about Total Homocysteine Determinations: An Expert Opinion. Clinical Chemistry 2004; 50:1 3- 32.

⁴Kuzminski AM, Del Giacco EJ, Allen RH, et al: Effective Treatment of Cobalamin Deficiency with Oral Cobalamin. Blood 1998; 92:1191- 1198.

⁵Troen AM, Mitchell B, Sorensen B, Wener MH, Johnston A, Wood B, Selhub J, McTiernan A, Yasui Y, Oral E, Potter JD, and Ulrich CM: Unmetabolized Folic Acid in Plasma is Associated with Reduced Natural Killer Cell Cytotoxicity among Postmenopausal Women. Journal of Nutrition 2006 Jan; 136(1): 189-194.

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Folbee® Tablets Medical Food

Each Folbee® Tablet contains:

Vitamin B₆ (as Pyridoxine HCl) 25 mg
Folacin (Folic Acid) 2.5 mg
Vitamin B₁₂ (as Cyanocobalamin) 1 mg

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

*Contains Carmine as a color additive.

Cyanocobalamin appears as dark red crystals or crystalline red powder. The chemical name is 5,6-dimethylbenzimidazolyl cyanocobamide. Its empirical formula is C₆₃H₈₈CoN₁₄O₁₄P.

Folacin (folic acid) is a yellowish-orange crystal. The chemical name is N-[4-[[[(2-Amino-1,4-dihydro-4-oxo-6-pteridiny)]methyl]amino]benzoyl]-L-glutamic acid. Its empirical formula is C₁₉H₁₉N₇O₆.

Pyridoxine hydrochloride appears either as a white crystal, a white crystalline powder or a colorless powder. It is stable in air and is slowly affected by sunlight. The chemical name is 3,4- pyridinedimethanol, 5-hydroxy-6-methyl-,hydrochloride. Pyridoxol hydrochloride. Its empirical formula is C₈H₁₁NO₃HCl.

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, homocystinuria, nutrient malabsorption or inadequate dietary intake; with particular emphasis on individuals with or at risk for: cardiovascular disease, cerebrovascular disease, peripheral vascular disease, arteriosclerotic vascular disease, neurological disorders, Alzheimer disease, and renal disease. Folbee® 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.

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.

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FOLIC ACID SUPPLEMENTATION:

The use of supplemental folacin (folic acid) may be indicated in patients with increased requirements for this vitamin. Folic acid administration may reduce the risk of neural tube defects in the developing fetus.

Folic acid has been shown to reduce circulating homocysteine levels in the blood. Folate as 5-methyltetrahydrofolate and B₁₂ as methylcobalamin participate in the remethylation reaction of homocysteine to methionine.

PRECAUTIONS:

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 1 mg of cyanocobalamin contained in Folbee® Tablets have been shown to provide an adequate amount of cyanocobalamin to address this precaution.

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

ADVERSE REACTIONS:

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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.

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

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