

# Folbic, Folbee and Folbee Plus Tablets



**ATTENTION HEALTHCARE PROVIDER:**  
 If your patients are looking for a cost-effective combination of Folic Acid with B6 & B12 or Folic Acid and Multiple Vitamin therapy, then consider **Folbic, Folbee and Folbee Plus.**



NDC# (51991) -	BRECKENRIDGE PRODUCT	EACH TABLET CONTAINS	DETAILED DESCRIPTION	SIZE
384-90	Folbic Tablets	Folacin (Folic Acid) 2.5mg Pyridoxine HCl (B6) 25mg Cyanocobalamin (B12) 2mg	Rose Colored, Oval Tablet Debossed B 384	90
084-90	Folbee Tablets	Folacin (Folic Acid) 2.5mg Pyridoxine HCl (B6) 25mg Cyanocobalamin (B12) 1mg	Natural Orange, Oval Tablet Debossed B 084	90
082-90	Folbee Plus Tablets	Folacin (Folic Acid) 5mg Vitamin B12 (Cyanocobalamin) 1mg Vitamin B1 (Thiamine HCl) 1.5mg Vitamin B-2 (Riboflavin) 1.5mg Vitamin B-6 (Pyridoxine HCl) 50mg Niacin (Niacinamide) 20mg Vitamin C (Ascorbic Acid) 60mg Pantothenic Acid (Calcium Pantothenate) 10mg Biotin 300mcg	Yellow, Film Coated, Capsule Shaped Tablet Debossed B 082	90

## IMPORTANT FACTS ABOUT FOLBIC, FOLBEE AND FOLBEE PLUS

- Please note, Folbic Tablets, Folbee Tablets and Folbee Plus Tablets are not FDA Approved Products, and therefore, are not in the Orange Book.\*
- If you choose to substitute Folbic Tablets, Folbee Tablets or Folbee Plus Tablets, you must do so in accordance with the laws of your state; which in many states means that you must contact the prescribing physician and get a new prescription.
- As always, Breckenridge reminds its pharmacy partners, that all prescription substitutions shall be pursuant to individual state statutes as applicable.
- If you have other questions, or would like additional information, please give us a call.

**For more information on these products, or any of our other 150 SKU's, contact your wholesaler or distributor or visit us at [www.folbee.com](http://www.folbee.com).**



**Breckenridge  
 Pharmaceutical, Inc.**  
 "Your Value Brand Company"  
 Boca Raton, FL 33487

Phone (800) 814-4349  
 Fax: (800) 814-3291  
 email: [info@folbee.com](mailto:info@folbee.com)

Please see full prescribing information concerning **Folbic, Folbee and Folbee Plus**, as well as important patent information concerning **Folbic** on back.

## Folbic Tablets (Rx Only)

### DESCRIPTION

Each rose colored tablet contains: Folicin (Folic Acid USP) 2.5 mg, cyanocobalamin USP (B12) 2 mg., and pyridoxine HCl USP (B6) 25 mg. **Folbic Tablets do not contain sugar or lactose.**

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

Cyanocobalamin appears as dark red crystals or crystalline red powder. The chemical name is 5,6-dimethylbenzimidazolyl cyanocobamide. Its empirical formula is  $C_{63}H_{88}CoN_{14}O_{14}P$ .

Folicin (folic acid) is yellowish-orange crystal. The chemical name is N-[4[[[(2-Amino-1,4-dihydro-4-oxo-6-ptendiny)]methyl]-amino]benzoyl]-L-glutamic acid. Its empirical formula is  $C_{19}H_{19}N_7O_6$ .

Pyridoxine hydrochloride is a colorless or white crystal or a white crystalline 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  $C_8H_{11}NO_3HCl$ .

### INDICATION AND USAGE:

Folbic Tablets are indicated for the distinctive nutritional requirements of individuals under a physician's treatment for vitamin deficiencies.

### FOLIC ACID SUPPLEMENTATION:

The use of supplemental folicin (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.

### PRECAUTIONS:

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 Folbic Tablets has been shown to provide an adequate amount of cyanocobalamin to address this precaution.

### ADVERSE REACTIONS:

Allergic sensitization has been reported following both oral and parenteral administration of folicin (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.

**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.**

### DRUG INTERACTIONS:

Pyridoxine supplements should not be given to patients receiving levodopa, because the action of the latter drug 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:

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

### DOSAGE AND ADMINISTRATION:

1 or 2 Tablet(s) daily or as directed by a physician.

**HOW SUPPLIED:** Folbic Tablets are available as an oval rose colored tablet, embossed B 384. Supplied in bottles of 90 Tablets, NDC# 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 original light-resistant container with child-resistant closure.

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

### Rx Only

**Manufactured by:** Contract Pharmaceutical Corp., Hauppauge, NY 11788

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

## Folbee Tablets (Rx Only)

### DESCRIPTION

Each natural orangish colored tablet contains folicin (folic acid USP) 2.5 mg, cyanocobalamin USP (B12) 1 mg, and pyridoxine HCl USP (B6) 25 mg. **Folbee Tablets do not contain sugar or lactose.**

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

Cyanocobalamin appears as dark red crystals or crystalline red powder. The chemical name is 5,6-dimethylbenzimidazolyl cyanocobamide. Its empirical formula is  $C_{63}H_{88}CoN_{14}O_{14}P$ .

Folicin (folic acid) is yellowish-orange crystal. The chemical name is N-[4[[[(2-Amino-1,4-dihydro-4-oxo-6-ptendiny)]methyl]-amino]benzoyl]-L-glutamic acid. Its empirical formula is  $C_{19}H_{19}N_7O_6$ .

Pyridoxine hydrochloride is a colorless or white crystal or a white crystalline 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  $C_8H_{11}NO_3HCl$ .

### INDICATION AND USAGE:

Folbee Tablets are indicated for the distinctive nutritional requirements of individuals under physician's treatment for vitamin deficiencies.

### FOLIC ACID SUPPLEMENTATION:

The use of supplemental folicin (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.

### PRECAUTIONS:

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

### ADVERSE REACTIONS:

Allergic sensitization has been reported following both oral and parenteral administration of folicin (folic acid). Paresthesia, 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.

**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.**

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

### PATIENT INFORMATION:

Folbee 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 or as directed by physician.

**HOW SUPPLIED:** Folbee Tablets are available as an oval natural orangish colored tablet, debossed B 084. Supplied in bottles of 90 Tablets, NDC# 51991-084-90.

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 original light-resistant container with child-resistant closure.

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

### Rx Only

**Distributed by:** Breckenridge Pharmaceutical, Inc.

**Manufactured by:** Contract Pharmaceutical Corp.

Boca Raton, FL 33487

Hauppauge, NY 11788

## Folbee Plus Tablets (Rx Only)

### DESCRIPTION

Each film coated yellow tablet contains:

Folicin (Folic Acid) .....	5mg.
Cyanocobalamin (Vitamin B12) .....	1mg.
Thiamine HCl (Vitamin B1) .....	1.5mg.
Riboflavin (Vitamin B2) .....	1.5mg.
Pyridoxine HCl (Vitamin B6) .....	.50mg.
Niacinamide (Niacin) .....	.20mg.
Ascorbic Acid (Vitamin C) .....	.60mg.
Calcium Pantothenate (Pantothenic Acid) .....	.10mg.
Biotin .....	.300mcg.

**Folbee Plus Tablets do not contain sugar or lactose.**

### INACTIVE INGREDIENTS

Croscarmellose Sodium, Dicalcium Phosphate, Hydroxypropyl Methylcellulose, Magnesium Silicate, Magnesium Stearate, Microcrystalline Cellulose, Mineral Oil, Riboflavin, 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 vitamin deficiencies.

### 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 has been shown to provide an adequate amount of cyanocobalamin to address this precaution.

### ADVERSE REACTIONS:

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. Paresthesia, 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.

**WARNINGS: 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.**

### 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 or as directed by physician.

**HOW SUPPLIED:** Available as capsule shaped, film coated, yellow tablets. Debossed with B 082. Supplied in bottles of 90 tablets, NDC #51991-082-90. Protect from light and moisture. Dispense in original light-resistant container with child-resistant closure. Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature.

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

### Rx Only

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Contract Pharmacal Corp.

Boca Raton, FL 33487

Hauppauge, NY 11788



## BUCKINGHAM, DOOLITTLE & BURROUGHS, LLP

Attorneys & Counselors at Law

2500 North Military Trail Suite 480 Boca Raton, FL 33431  
561.241.0414 TollFree 800.682.2825 Fax 561.989.3710 www.bdbllaw.com

Robert E. Pershes  
E-mail: rpershes@bdbllaw.com

December 15, 2004

Re: FOLBEE and FOLBIC  
Breckenridge Pharmaceutical, Inc.

Dear Pharmaceutical Professional:

This office is counsel to Breckenridge Pharmaceutical Inc. ("Breckenridge"). Breckenridge is the distributor of the products known as Folbee and Folbic, which are utilized for treating vitamin deficiencies.

Folbee contains Folicin (Folic Acid) 2.5 mg., Pyridoxine HCL (B6) 25 mg. and Cyanocobalamin (B12) 1 mg., and Folbic contains Folicin (Folic Acid) 2.5 mg., Pyridoxine HCL (B6) 25 mg. and Cyanocobalamin (B12) 2 mg.

Pamlab has previously asserted that Folbee infringed patents held by its licensor Metabolite. On December 23, 2003 in a suit instituted by Metabolite against Breckenridge, the United States District Court for the District of Colorado unequivocally DENIED the request for injunctive relief made by Pamlab and Metabolite, or any relief to impede sales of FOLBEE. Further, after a strong showing by Breckenridge's attorneys, the Complaint was fully withdrawn by Pamlab and Metabolite. Now Pamlab and Metabolite assert that Folbic infringes a patent held by Metabolite for a "composition for treating, preventing or reducing elevated metabolic levels".

Folbic in accordance with its labeling is for use in vitamin deficiencies and is not believed to infringe any valid United States patent in connection with such usage.

Breckenridge has instituted suit in the United States District Court, Southern District of Florida to eliminate any confusion with regard to this issue. Please do not hesitate to contact Breckenridge in connection with questions you may have regarding the proper usage of any Breckenridge product.

Very truly yours,

Robert E. Pershes

REP:sj

cc: Breckenridge Pharmaceutical, Inc.

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Akron  
Boca Raton  
Canton  
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Columbus