

FOLTX[®] Tablets

A medical food for the dietary management of hyperhomocysteinemia.

Description

Each round coated beige colored tablet contains:

Active Ingredients:

| | |
|--------------------------------|--------|
| Folacin (folic acid) | 2.5 mg |
| Pyridoxine (as pyridoxine HCl) | 25 mg |
| Cyanocobalamin | 2 mg |

Inactive Ingredients:

Dibasic Calcium Phosphate Dihydrate, Microcrystalline Cellulose, Opadry II Beige 40L17427 (Titanium Dioxide, Polydextrose, Hypromellose 3cP, Hypromellose 6cP, Triacetin, Hypromellose 50cP, Polyethylene Glycol 8000, FD&C Yellow # 6-Lake, FD&C Blue # 2-Lake, FD&C Red #40-Lake), Crospovidone, Croscarmellose Sodium, Magnesium Stearate (Vegetable Source), Opadry II Clear #Y-19-7483 (Hypromellose 6cP, Maltodextrin, Hypromellose 3cP, PEG 400, Hypromellose 50cP).

FOLTX[®] tablets do not contain sugar, or lactose.

Indication and Usage

FOLTX[®] tablets are indicated for the distinct nutritional requirements of individuals under a physician's treatment 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.

Precautions

Folacin (folic acid) when administered as a single agent in doses above 0.1mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. The 2 mgs of cyanocobalamin contained in FOLTX[®] 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 (50-75yrs) 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.

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. Warfarin can produce significant impairment in folate status after a 6-month therapy.

Patient Information

FOLTX[®] 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 to two tablets daily or as directed by a physician.

How Supplied

Available as a round coated beige colored tablet. Debossed with "PAL" on one side and "♥" (heart outline) on the other. Supplied in bottles of 90 tablets.

Storage

Store at controlled room temperature between 15°-30° C (59°-86° F) (See USP). Protect from light and moisture. Dispense in original light-resistant container with child resistant closure.

00525-0906-90*

*Pamlab LLC does not represent this product code to be actual National Drug Codes (NDCs). NDC format codes are product codes adjusted to meet the formatting requirements of pharmacy and health insurance computer systems.

Available by Prescription

Some or all of the following patents may apply:

U.S. Patent No. 4,940,658 U.S. Patent No. 6,207,651

U.S. Patent No. 5,563,126 U.S. Patent No. 6,297,224

U.S. Patent No. 5,795,873 U.S. Patent No. 6,528,496

and other pending patent applications.

References

^{1,2}Eilleboom JW, Lonna 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.

³The Homocysteine Studies Collaboration: Homocysteine and Risk of Ischemic Heart Disease and Stroke. JAMA 2002; Vol 288, No. 16:2015-2002.

⁴Refsum Helga, Smith A. David, Ueland Per M, Nexo Ebba, Clarke Robert, McPartlin Joseph, Johnston Carole, Engbaek Frode, Scheede Jorn, McPartlin Catherime, and Scott John M.: Facts and Recommendations about Total Homocysteine Determinations: An Expert Opinion. Clinical Chemistry 2004; 50:1 3-32.

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

⁶Troen AM, Mitchell B, Sorensen B, Wener MH, Johnston A, Wood B, Selhub J, McTierman A, Yasui Y, Oral E, Potter JD, and Ulich 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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