FOLTX® Prescribing Information

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	(B_6)	25 mg
Cyanocobalamin	(B_{12})	2 mg

Inactive Ingredients:
Dibasic Calcium Phosphate Dihydrate, Microcrystalline Cellulose, Opadry II Beige 40L174427 (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 coronary[1], peripheral[2], or cerebral[3] vessels, or vitamin B_{12} deficiency[4].

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 precaution[5]. 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 response[6].
Cyanocobalamin should not be used in those with Leber's optic atrophy. Decreased levels of B_{12} 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 B_{12} is an acceptable form for B_{12} supplementation in those with this disorder.
Pregnant women and nursing mothers should only use 12 microgram doses of B_{12} (cyanocobalamin) from nutritional supplements. Doses higher than this should only be recommended by your physician.
Administration of doses of vitamin B_{12} 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.

Reactions To Drugs
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
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.
NDC# 00525-0906-90

RX ONLY

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]Eilelboom 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.

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

[4]Refsum 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.

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

[6]Troen 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 Cytoxicity among Postmenopausal Women. Journal of Nutrition 2006 Jan; 136(1): 189-194.

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