METANX FC™ Capsules

A medical food for the dietary management of peripheral neuropathy and diabetic ulcer.

DESCRIPTION

Each clear capsule contains:

Dietary Ingredients:

L-methylfolate Calcium (Metafolin®) 3 mg Pyridoxal-5´-Phosphate 35 mg Methylcobalamin 2 mg

Other Ingredients:

Microcrystalline Cellulose and Silicon Dioxide, Vegetarian Capsule (Hypromellose, Carrageenan, Potassium Acetate, Black Iron Oxide, Hydroxypropyl Cellulose), Pyridoxal-5-Phosphate, L-methylfolate Calcium, Methylcobalamin, Magnesium Stearate (Vegetable Source).

- Free from Common Allergens: Fish, Shellfish, Wheat, Eggs, Milk, Tree Nuts, Peanuts, Soy and Sesame.
- Free from Dyes
- Free from Preservatives
- Free from Sugar
- Free from Titanium Dioxide
- Free from Sodium
- Non GMO
- Vegan

INDICATIONS AND USAGE CLINICAL DIETARY MANAGEMENT OF PERIPHERAL NEUROPATHY

METANX FC™ is indicated for the distinct nutritional requirements of individuals with endothelial dysfunction who present with loss of protective sensation associated with peripheral neuropathy.¹-6

CLINICAL DIETARY MANAGEMENT OF DIABETIC ULCER

METANX FC[™] is indicated for the distinct nutritional requirements of patients with endothelial dysfunction and/or hyperhomocysteinemia who present with lower extremity ulceration(s).^{7-10, 16}

PRECAUTIONS

Folic acid, when administered in daily doses above 0.1mg, may obscure the detection of B12

deficiency (specifically, the administration of folic acid may reverse the hematological manifestations of B12 deficiency, including pernicious anemia, while not addressing the neurological manifestations). L-methylfolate Calcium may be less likely than folic acid to mask vitamin B12 deficiency. ^{11,12} Folate therapy alone is inadequate for the treatment of a B12 deficiency.

ADVERSE REACTIONS

Allergic reactions have been reported following the use of oral L-methylfolate Calcium. Acne, skin reactions, allergic reactions, photosensitivity, nausea, vomiting, abdominal pain, loss of appetite, increased liver function test results, paresthesia, somnolence, nausea, and headaches have been reported with pyridoxal 5'-phosphate. Mild transient diarrhea, itching, transitory exanthema and the feeling of swelling of the entire body has been associated with methylcobalamin.

CONTRAINDICATIONS

METANX FC[™] is contraindicated in patients with known hypersensitivity to any of the components contained in this product.

PATIENT INFORMATION

METANX FC[™] is a medical food for use under medical supervision.

RECOMMENDED USE

Usual adult dose may be taken as one capsule twice daily (1 capsule B.I.D.); or two capsules once daily (2 capsules QD) or as directed by a healthcare provider.

HOW SUPPLIED

Commercial Product (90 capsules) 00525-8110-90

Commercial Product (180 capsules) 00525-8110-18 Rx

Professional Sample (6 capsules)
00525-8110-06
Not for Sale

Rx

Available as a clear capsule. It is imprinted with "Metanx" in black ink on the cap.

STORAGE

Store at controlled room temperature 15°C to 30°C (59°F to 86°F) (See USP). Protect from heat, light and moisture.

Metafolin® is a trademark of Merck KGaA, Germany

Manufactured and Distributed by Alfasigma USA, Inc. Shreveport, LA 71103

Questions? Call 1-866-331-6440

REFERENCES

- ^{1.} Verhaar M.C., et al. Circulation 1998;97:237-241.
- ² Van Etten R.W., et al. Diabetologia 2002;45:1004-1010.
- ^{3.} Romerio S.C., et al. Atherosclerosis 2004;176:337-344.
- ^{4.} Walker MJ Jr, et al. Rev Neurol Dis 2010;7(4):132-139.
- ^{5.} Jacobs AM, Cheng D. J Diabetes Mellitus. 2013;3(3):134-138.
- ^{6.} Li G. Beijing Methylcobal Clinical Trial Collaborative Group. Zhonghua Nei Ke Za Zhi 1999;38(1):14-17.
- ^{7.} Ambrosch A. et al. Diabet Med. 2001;18:185-192.
- 8. Veves A., et al. Diabetes 1998;47:457-463.
- ^{9.} Boykin J.V. Jr. Vascular Disease Management 2007;2(1):1-8.
- ^{10.} Boykin J.V. Jr., Byalis C.Wounds 2006;18(4):101-116.
- ^{11.} B Akoglu, et al. European Journal of Clinical Nutrition (2007), 1-6.
- ^{12.} Scott JM, et al. Lancet. 1981 2:337-340.
- ^{13.} Natural Standard Research Collaboration (NIH Folate (folic acid) Monograph 2009.
- ¹⁴ Alternative Medicine Review Vitamin B6 Monograph Volume 6, Number 1, 2001.
- ^{15.} Natural Standard Research Collaboration (NIH). Vitamin B12Monograph 2009.
- ^{16.} Boykin J.V. Jr. Wound Rep Reg 2020;28:517-525

Revised: (05/2024)