

METANX® Capsules

DESCRIPTION

METANX® is a prescription medical food for use only under the supervision of a physician for the clinical dietary management of diabetic peripheral neuropathy and is specially formulated to meet the distinctive nutritional requirements for this condition.

Each METANX® capsule contains 3 mg of L-methylfolate Calcium (as Metafolin®)*, 90.314 mg of Algae-S Powder (Schizochytrium), 35 mg of Pyridoxal-5'-Phosphate and 2.0 mg of Methylcobalamin *CAS#151533-22-1

INGREDIENTS

Silicified Microcrystalline Cellulose, Algae-S Powder [Schizochytrium Algal Oil (Vegetable Source), Glucose Syrup Solids, Mannitol, Sodium Caseinate (Milk), Soy Protein, High Oleic Sunflower Oil, 2% or less Sodium Ascorbate, Tricalcium Phosphate, Tetrasodium Diphosphate, Natural Flavors, Soy Lecithin, and Mixed Natural Tocopherols and Ascorbyl Palmitate (as antioxidants)], Pullulan, Pyridoxal 5'- Phosphate, L-methylfolate Calcium, Methylcobalamin, Titanium Dioxide (color), Magnesium Stearate (Vegetable Source), Caramel (color), Riboflavin USP, Shellac, Propylene Glycol USP. **Contains Milk and Soy**

METANX® capsules do not contain lactose, yeast or gluten.

METANX® is a prescription medical food for use only under the supervision of a physician.

Medical foods are intended for a patient who has a 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 the normal diet alone.¹ **This product is not an Orange Book product.**

INDICATIONS AND USAGE

METANX® is indicated for the distinct nutritional requirements of individuals with endothelial dysfunction who present with loss of protective

sensation and neuropathic pain associated with diabetic peripheral neuropathy.²⁻⁷

METANX® is indicated for the distinct nutritional requirements of patients with endothelial dysfunction and/or hyperhomocysteinemia who present with lower extremity ulceration(s).⁸⁻¹¹

CONTRAINDICATIONS

METANX® is contraindicated in patients with known hypersensitivity to any of the components contained in this product.

PRECAUTIONS

GENERAL

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.^{12,13} Folate therapy alone is inadequate for the treatment of a B12 deficiency.

PATIENT INFORMATION

METANX® is a prescription medical food for use only under the supervision of a physician.

ADVERSE REACTIONS

Allergic reactions have been reported following the use of oral L-methylfolate Calcium.¹⁴ 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.¹⁵ Mild transient diarrhea, itching, transitory exanthema and the feeling of swelling of the entire body has been associated with methylcobalamin.¹⁶

RECOMMENDED USE

The 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 under medical supervision.

HOW SUPPLIED

METANX® is a prescription medical food for use only under the supervision of a physician.

METANX® Bottle of 90 Product Code # 00525-8049-90*. Use under medical supervision.

METANX® Bottle of 180 Product Code # 00525-8049-18*. Use under medical supervision.

Each METANX® capsule has an opaque caramel cap and opaque white body. It is imprinted with "Metanx" in red ink on the body.

*Alfasigma USA, Inc. does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirements of pharmacy and health insurance computer systems.

STORAGE

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

PATENTS

Some or all of the following patents may apply:

- U.S. Patent No. 5,997,915
- U.S. Patent No. 6,011,040
- U.S. Patent No. 6,254,904
- U.S. Patent No. 6,441,168B1
- U.S. Patent No. 6,673,381
- U.S. Patent No. 7,172,778
- U.S. Patent No. 7,674,490
- U.S. Patent No. 8,129,172
- U.S. Patent No. 7,579,174
- U.S. Patent No. 7,732,170
- U.S. Patent No. 8,124,384
- U.S. Patent No. 8,124,385
- U.S. Patent No. 8,133,706

REFERENCES

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Revised 2/17