

METANX® Capsules

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

DESCRIPTION

Each opaque caramel/white capsule contains:

Dietary Ingredients:

L-methylfolate Calcium (Metafolin®)	3 mg
Algae S Powder (Schizochytrium)	90.314 mg
Pyridoxal-5'-Phosphate	35 mg
Methylcobalamin	2 mg

Other Ingredients:

Silicified Microcrystalline Cellulose 90, Algae-S Powder (Schizochytrium Algal Oil [Vegetable source]), Glucose Syrup Solids, Mannitol, Sodium Caseinate, Soy Protein, High Oleic Sunflower Oil, Sodium Ascorbate, Natural Flavors, Tricalcium Phosphate, Tetrasodium Diphosphate, Tocopherols, Soy Lecithin, Ascorbyl Palmitate, Gelatin, Pyridoxal-5-Phosphate, L-methylfolate Calcium, Methylcobalamin, Magnesium Stearate, Titanium Dioxide, Caramel 1, Sodium Lauryl Sulfate, Carmine Red Powder, Butyl Alcohol, Isopropyl Alcohol, Propylene Glycol, Shellac, Dehydrated Alcohol, Ammonia Solution

METANX® Capsules contain Milk and Soy.

INDICATIONS AND USAGE

CLINICAL DIETARY MANAGEMENT OF PERIPHERAL NEUROPATHY

METANX® is indicated for the distinct nutritional requirements of individuals with endothelial dysfunction who present with loss of protective sensation associated with peripheral neuropathy.¹⁻⁸

CLINICAL DIETARY MANAGEMENT OF DIABETIC ULCER

METANX® is indicated for the distinct nutritional requirements of patients with endothelial dysfunction and/or hyperhomocysteinemia who present with lower extremity ulceration(s).^{9-12, 18}

ADVERSE REACTIONS

Allergic reactions have been reported following the use of oral L-methylfolate Calcium.¹⁵ 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.¹⁶ Mild transient diarrhea, itching, transitory exanthema and the feeling of swelling of the entire body has been associated with methylcobalamin.¹⁷

CONTRAINDICATIONS

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

PATIENT INFORMATION

METANX® 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)	
00525-8049-90	Rx

Commercial Product (180 capsules)	
00525-8049-18	Rx

Available as an opaque caramel capsule and opaque white body. It is imprinted with "Metanx" in red ink on the body.

STORAGE

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

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.^{13,14} Folate therapy alone is inadequate for the treatment of a B12 deficiency.

REFERENCES

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Questions?

Call 1- 855-805-2530 (M-F 8AM to 5PM EST)

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