

Foltanx™ RF

Foltanx™ RF is a medical food for the dietary management of endothelial dysfunction.

DESCRIPTION

Each opaque white/caramel capsule contains:

3 mg of L-methylfolate Calcium (as Metafolin®)*, 90.314 mg of Algae-S Powder** (Schizochytrium), 35 mg of Pyridoxal-5'-Phosphate, 2.0 mg of Methylcobalamin

* CAS#151533-22-1

Other Ingredients:

Silicified Microcrystalline Cellulose, Pullulan, Titanium Dioxide (color), Magnesium Stearate (Vegetable Grade), Caramel (color), Riboflavin, Shellac, Propylene Glycol.

**Other Ingredients in Algae-S Powder (Schizochytrium) include: 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).

Foltanx™ RF contains Milk, Soy.

Foltanx™ RF is labeled as a medical food for use under the active and ongoing medical supervision of a physician or health-care provider on a recurring basis for, among other things, instructions on their use.

Medical foods are intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has 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 Medical Food is not subject to NDA or ANDA approval and is not an Orange Book product. Although FDA does not require a prescription for Medical Foods, this product is intended to be used under active medical supervision. This product is not eligible for government reimbursement under federal programs, but is eligible for reimbursement under state programs on a case-by-case basis. Please check with a specific state to determine proper reimbursement eligibility.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

INDICATIONS AND USAGE

Foltanx™ RF is indicated for the distinct nutritional requirements of patients with endothelial dysfunction.^{2,3,4}

Foltanx™ RF is indicated for the distinct nutritional requirements of patients with hyperhomocysteinemia.

Foltanx™ RF is recommended for use under medical supervision of a physician or health-care provider.

CONTRAINDICATIONS

Foltanx™ RF is contraindicated in patients with known sensitivity to any of the components in this product.

PRECAUTIONS

General:

Folic acid, when administered as a single agent in doses above 0.1 mg daily, may obscure the detection of B₁₂ deficiency. Folate therapy alone may be inadequate for the treatment of a B₁₂ deficiency.

Patient Information:

Foltanx™ RF is a medical food recommended for use under medical supervision of a physician or health-care provider.

ADVERSE REACTIONS

Allergic reactions have been reported following the use of oral L-methylfolate Calcium.⁵ 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.⁶ Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body have been associated with methylcobalamin.⁷

Keep this and all medications out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

DO dosage AND ADMINISTRATION

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

Each Foltanx™ RF capsule has a caramel cap and an opaque white body. It is imprinted with "B" in red ink on the cap and "913" in red ink on the body.

Bottles of 90 capsules Product Code 51991-913-90*** Use under supervision of a physician or health-care provider.

*** Breckenridge Pharmaceutical, Inc. does not represent this product code to be a National Drug Code (NDC) number. Product Codes are formatted according to standard industry practice, to meet the formatting requirements of pharmacy and health insurance computer systems.

Storage:

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature. Protect from heat, light and moisture.

PATENTS

For information on applicable patents, please visit www.bpirx.com

REFERENCES

¹ United States Food and Drug Administration Title 21 Code of federal Regulations 101.9(j)(8).

² Verhaar M.C., et al. *Circulation* 1998; 97:237-241.

³ van Etten R.W., et al. *Diabetologia* 2002; 45:1004-1010.

⁴ Romero S.C., et al. *Atherosclerosis* 2004; 176:337-344.

⁵ Natural Standard Research Collaboration (NIH). Folate (folic acid) Monograph 2009

⁶ Alternative Medicine Review Vitamin B6 Monograph Volume 6, Number 1, 2001

⁷ Natural Standard Research Collaboration (NIH). Vitamin B12 Monograph 2009

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To report a serious adverse event contact: 1-800-367-3395

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