

FOLBIC® RF

DESCRIPTION

FOLBIC® RF is a medical food for the dietary management of hyperhomocysteinemia.

Each round, coated, beige colored tablet contains:

L-methylfolate Calcium (as Metafolin®)*...1.13mg

Pyridoxine HCl....25mg

Cyanocobalamin 2mg

*CAS#151533-22-1

Other Ingredients:

Silicified Microcrystalline Cellulose NF, Opadry II Beige 40L17427 [color] (hypromelloses, titanium dioxide [color], polydextrose, triacetin, polyethylene glycol 8000, FD&C yellow No. 6** aluminum lake [color], FD&C blue No. 2 aluminum lake [color], FD&C red No. 40 aluminum lake [color]), Magnesium Stearate (Vegetable Source), Carnauba Wax

**Contains FD&C Yellow No. 6 as a color additive.

FOLBIC® RF does not contain lactose, sugar or gluten.

Folbic® 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 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

FOLBIC® RF is indicated for the distinct nutritional requirements of individuals with hyperhomocysteinemia.^{2,3,4}

CONTRAINDICATIONS

FOLBIC® RF 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. L-methylfolate Calcium may be less likely than folic acid to mask vitamin B₁₂ deficiency.^{5,6} Folate therapy alone is inadequate for the treatment of a B₁₂ deficiency.

Patient Information:

FOLBIC® RF is a medical food recommended for use under medical supervision of a physician or healthcare provider.

ADVERSE REACTIONS

Allergic reactions have been reported following the use of oral L-methylfolate Calcium.⁷ 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 pyridoxine HCl.⁸ Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body has been associated with cyanocobalamin.⁹

Keep this and all medications out of the reach of children.

DOSAGE AND ADMINISTRATION

The usual adult dose may be taken as one **or** two tablets daily; **or** as directed by a physician or healthcare provider.

HOW SUPPLIED

FOLBIC® RF is recommended for use under medical supervision of a physician or healthcare provider. Each round, coated, beige colored tablet is debossed with "LMF" on one side and "1" on the other side.

Bottles of 90 tablets

51991-616-90***

***Breckenridge Pharmaceutical, Inc. does not represent this product code to be 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 15°C to 30°C (59°F to 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. Flicker L, et al. Stroke. 2006; 37:547-549.
3. Homocysteine Lowering Trialist's Collaboration. Br. Med J. 1998; 316:894-898
4. Meleady R, et al. Am J Clin Nutr 2003;77:63-70.
5. B Akoglu, et al. European Journal of Clinical Nutrition (2007), 1-6
6. Scott JM, et al. Lancet. 1981 2:337-340
7. Natural Standard Research Collaboration (NIH). Folate (folic acid) Monograph 2009
8. Alternative Medicine Review Vitamin B6 Monograph Volume 6, Number 1, 2001
9. Natural Standard Research Collaboration (NIH). Vitamin B12 Monograph 2009

Metafolin® is a registered trademark of Merck KGaA, Darmstadt, Germany.

All the registered trademarks used herein are the property of their respective owners.

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

Distributed by:

Breckenridge Pharmaceutical, Inc.
Boca Raton, FL 33487

Manufactured by:

Nestlé Health Science - Pamlab, Inc.
Shreveport, LA 71103

Revised 11/16

PC0376-00