

## Metafolbic™ Plus RF Caplets

### DESCRIPTION

**Metafolbic™ Plus RF** Caplets are a medical food recommended for use under the supervision of a physician or health-care provider.

Each beige colored caplet contains: 6 mg of L-methylfolate Calcium (as Metafolin®), 90.314 mg of Algae-S Powder (*Schizochytrium*)\*\*, 2 mg of Methylcobalamin and 600 mg of N-Acetyl-L-Cysteine.

\*CAS#1515333-22-1

### Other Ingredients:

Silicified Microcrystalline Cellulose, Polyvinyl Alcohol, Titanium Dioxide [color], Croscarmellose Sodium, PEG 3350, Talc, Magnesium Stearate (Vegetable Grade), Beet Powder (Red), Caramel [color], and Carnauba Wax.

\*\* 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. **Metafolbic™ Plus RF** Caplets contain Milk and Soy.

**Metafolbic™ Plus RF** Caplets do not contain gluten or yeast.

**Metafolbic™ Plus RF** Caplets are a medical food recommended for use under the supervision of a physician or health-care provider.

**Metafolbic™ Plus RF** Caplets are labeled as a medical food for use under the active and ongoing medical supervision requiring medical care 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.<sup>1</sup> 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

**Metafolbic™ Plus RF** Caplets are indicated for the dietary management of individuals with distinct nutritional needs relating to hyperhomocysteinemia<sup>2-8</sup> and/or cognitive impairment; and/or suboptimal vitamin B<sub>12</sub> levels.

### CONTRAINDICATIONS

**Metafolbic™ Plus RF** Caplets are contraindicated in patients with known hypersensitivity to any of the components contained 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 B<sub>12</sub> deficiency. L-methylfolate Calcium may be less likely than folic acid to mask vitamin B<sub>12</sub> deficiency.<sup>9-10</sup> Folate therapy alone is inadequate for the treatment of a B<sub>12</sub> deficiency.

N-acetyl-L-cysteine should be avoided by nursing mothers.<sup>11</sup> N-acetyl-L-cysteine clearance is reduced in those with chronic liver disease as well as in pre-term newborns.<sup>11</sup> Headaches may be intensified in those taking N-acetyl-L-cysteine and nitrates for the treatment of angina.<sup>11</sup> While the incidence of renal stones is low, those that do form renal stones, particularly cysteine stones should avoid **Metafolbic™ Plus RF** Caplets.<sup>11</sup> Do not administer **Metafolbic™ Plus RF** Caplets to critically ill patients.<sup>11</sup> N-acetyl-L-cysteine and its sulfhydryl metabolites could produce a false-positive result in the nitroprusside test for ketone bodies used in diabetes.<sup>11</sup> N-acetyl-L-cysteine should be used with caution in those with a history of peptic ulcer disease since N-acetyl-L-cysteine may disrupt the gastric mucosal barrier.<sup>11</sup>

#### Patient Information:

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### ADVERSE REACTIONS

Allergic reactions have been reported following the use of oral L-methylfolate Calcium.<sup>12</sup> Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body has been associated with methylcobalamin.<sup>13</sup> Nausea, vomiting, diarrhea, transient skin rash, flushing, epigastric pain, and constipation have been associated with N-acetyl-L-cysteine.<sup>11</sup>

### DOSAGE AND ADMINISTRATION

The usual adult dose is one caplet daily or as directed under medical supervision.

### HOW SUPPLIED

**Metafolbic™ Plus RF** Caplets are a medical food recommended for use under the supervision of a physician or health-care provider.

**Metafolbic™ Plus RF** Caplets are available as oval coated beige colored caplets. Debossed with "LMF" on one side and "6RF" on the other side.

Bottles of 90 caplets 51991-911-90\*\*\*

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\*\*\*Breckenridge Pharmaceutical, Inc. does not represent these product codes to be National Drug Codes (NDCs). 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](http://www.bpirx.com)

### REFERENCES

1. United States Food and Drug Administration Title 21 Code of Federal Regulations 101.9(j) (8).
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  3. Albert M, et al. *Alzheimer's and Dementia* 2011; 1-10
  4. Boyd-Kimball D, et al. *Journal of Neuroscience Research* 2005;79:700-706.
  5. Guidi I, et al. *Neurobiology of Aging* 2006;27(2):262-269.
  6. Keller J, et al. *Neurology* 2005; 64:1152-1156.
  7. Wiklund O, et al. *Atherosclerosis* 119 (1996) 99-106.
  8. Durga J et al. *The Lancet* 2007;369:208-216.
  9. B Koglu, et al. *European Journal of Clinical Nutrition* (2007), 1-6
  10. Scott JM, et al. *Lancet*. 1981 2:337-340
  11. PDR for Nutritional Supplements 2001; ISBN: 1-56363-364-7; 11-14
  12. Natural Standard Research Collaboration (NIH). Folate (folic acid) Monograph 2009
  13. Natural Standard Research Collaboration (NIH). Vitamin B12 Monograph 2009
- Metafolin® is a registered trademark of Merck KGaA, Darmstadt, Germany.

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

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