

## L-Methylfolate Forte 7.5 mg

## L-Methylfolate Forte 15 mg

### DESCRIPTION

**L-Methylfolate Forte 7.5/15 mg** is a medical food for the dietary management of conditions relating to suboptimal L-methylfolate levels, recommended for use under the supervision of a physician or healthcare provider.

Each **L-Methylfolate Forte 7.5 mg capsule** contains 7.5 mg of L-methylfolate Calcium\* and 90.314 mg Algae-S Powder (Schizochytrium)\*\*.

\*CAS#151533-22-1

#### Other Ingredients:

Silicified Microcrystalline Cellulose, Pullulan, Titanium dioxide [color], Magnesium Stearate (Vegetable Source), FD&C Yellow #6[*color*], FD&C Red #40[*color*], Propylene Glycol, Sodium Hydroxide, Povidone, FD&C Yellow #6 Aluminum Lake[*color*], Shellac.

\*\*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, Natural Flavors, Tricalcium Phosphate, Tetrasodium Diphosphate, Mixed Natural Tocopherols, Soy Lecithin, and Ascorbyl Palmitate.

Each **L-Methylfolate Forte 15 mg capsule** contains 15 mg of L-methylfolate Calcium\* and 90.314 mg Algae-S Powder (Schizochytrium)\*\*.

\*CAS#151533-22-1

#### Other Ingredients:

Silicified Microcrystalline Cellulose, Gelatin (Kosher), Titanium Dioxide, Magnesium Stearate (Vegetable Grade), Shellac, Propylene Glycol, Carmine.\*\*\*

\*\*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, Natural Flavors, Tricalcium Phosphate, Tetrasodium Diphosphate, Mixed Natural Tocopherols, Soy Lecithin, and Ascorbyl Palmitate.

**L-Methylfolate Forte 7.5/15 mg contains Milk and Soy.**

\*\*\**L-Methylfolate Forte 15 mg contains Carmine as a color additive.*

**L-Methylfolate Forte 7.5/15 mg** 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.<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.**

**L-Methylfolate Forte 7.5/15 mg** is a medical food recommended for use under the supervision of a physician or health-care provider.

### INDICATIONS AND USAGE

**L-Methylfolate Forte 7.5/15 mg** is labeled as a medical food for the distinct nutritional requirements of individuals who have or are at risk for conditions relating to suboptimal L-methylfolate levels.

### CONTRAINDICATIONS

**L-Methylfolate Forte 7.5/15 mg** 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 0.1 mg, may obscure the detection of B<sub>12</sub> deficiency. L-methylfolate may be less likely than folic acid to mask vitamin B<sub>12</sub> deficiency.<sup>2,3</sup> Folate therapy alone is inadequate for the treatment of a B<sub>12</sub> deficiency.

#### Patient Information:

**L-Methylfolate Forte 7.5/15 mg** is a medical food recommended for use under the supervision of a physician or health-care provider.

### ADVERSE REACTIONS

Allergic reactions have been reported following the use of oral L-methylfolate.

**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.**

### DOSAGE AND ADMINISTRATION

The usual adult dose is one capsule given daily with or without food as directed under medical supervision.

### HOW SUPPLIED

**L-Methylfolate Forte 7.5/15 mg** is a medical food recommended for use under the supervision of a physician or health-care provider.

Each **L-Methylfolate Forte 7.5 mg capsule** has an orange cap and opaque white body. It is imprinted with "B" in white ink on the cap and "908" in orange ink on the body.

**L-Methylfolate Forte 7.5mg:** Bottles of 30 capsules, Product Code 51991-908-33<sup>‡</sup> and Bottles of 90 capsules, Product Code 51991-908-90<sup>‡</sup>. Use under medical/physician supervision.

Each **L-Methylfolate Forte 15 mg capsule** has an opaque white cap and opaque white body. It is imprinted with "15" in red ink on the cap and "AG" in red ink on the body.

**L-Methylfolate Forte 15mg:** Bottles of 30 capsules, Product Code 51991-909-33<sup>‡</sup> and Bottles of 90 capsules, Product Code 51991-909-90<sup>‡</sup>. Use under medical/physician supervision.

<sup>‡</sup>Breckenridge Pharmaceutical, 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 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)

### REFERENCE

1. United States Food and Drug Administration Title 21 Code of Federal Regulations 101.9(j) (8).
2. Akoglu B et al. Euro J Clin Nutrition. 2007;1-6.
3. Scott JM and Weir DG. The Lancet. 1981;2:337-40.

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

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Breckenridge Pharmaceutical, Inc.

Berlin, CT 06037

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