Metafolbic™ Tablets

A medical food for the dietary management of hyperhomocysteinemia.

Description

Each round coated blue colored tablet contains:

Dietary Ingredients:

L-methylfolate Calcium (as Metafolin®)*	6 mg
Riboflavin	5 mg
Pyridoxine (as Pyridoxine HCl)	50 mg
Cyanocobalamin	1 mg

*CAS#151533-22-1

Other Ingredients:

Microcrystalline Cellulose, Opadry II Blue 40L10890 [color] (Hypromelloses, Polydextrose, FD&C Blue No. 1 [color], Triacetin, Titanium Dioxide [color], PEG 8000), Stearic Acid (Vegetable Grade), Croscarmellose Sodium, Silicon Dioxide, Magnesium Stearate (Vegetable Grade), Opadry II Clear No. Y-19-7483 (Hypromelloses, Maltodextrin, PEG 400).

Metafolin® (L-methylfolate calcium) is a substantially diastereoisomerically pure source of L-methylfolate containing not more than 1% D-methylfolate which results in not more than 0.06 milligrams of D-methylfolate in Metafolbic™.

Metafolbic™ tablets do not contain sugar, lactose, yeast or gluten.

Indication and Usage

Metafolbic™ Tablets are indicated for the distinct nutritional requirements of individuals under medical supervision for hyperhomocysteinemia.

Metafolbic™ 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. 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.

Precautions

Folates, when administered as a single agent in doses above 0.1 mg daily, may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive.

Adverse Reactions

While allergic sensitization has been reported following both oral and parenteral administration of folic acid, allergic sensitization has not been reported with the use of Metafolin®. Paresthesia, somnolence, nausea and headaches have been reported with pyridoxine. Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body has been associated with cyanocobalamin. Transient headaches have been reported infrequently with the use of **Metafolbic™**. If headaches should occur with the use of **Metafolbic™** consult with your medical practitioner.

Contraindications

Known hypersensitivity to any of the components in the product is a contraindication.

Drug Interactions

Metafolbic™ added to other drugs: High dose folic acid may result in decreased serum levels for pyrimethamine and first-generation anticonvulsants (carbamazepine, fosphenytoin, phenytoin, phenobarbital, primidone, valproic acid, valproate). This may possibly reduce first generation anticonvulsants effectiveness and/or increasing the frequency of seizures in susceptible patients. While the concurrent use of folic acid and first generation anticonvulsants or pyrimethamine may result in decreased efficacy of anticonvulsants, no such decreased effectiveness has been reported with the use of L-methylfolate. Nevertheless, caution should be used with **Metafolbic™** among patients who are receiving treatment with first generation anticonvulsants or pyrimethamine. Pyridoxine should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxine. However, pyridoxine may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa. Capecitabine (Xeloda®) toxicity may increase with the addition of leucovorin (5-formyltetrahydrofolate) (folate).

Drugs added to Metafolbic™: Antibiotics may alter the intestinal microflora and may decrease the absorption of cyanocobalamin. Cholestyramine, colchicines or colestipol may decrease the enterohepatic reabsorption of cyanocobalamin. Metformin, para-aminosalicylic acid and potassium chloride may decrease the absorption of cyanocobalamin. Nitrous oxide can produce a functional cyanocobalamin deficiency. Several drugs are associated with lowering serum folate levels or reducing the amount of active folate available. First generation anticonvulsants (carbamazepine, fosphenytoin, phenytoin, phenobarbital, primidone, valproic acid, valproate) and lamotrigine (a second-generation anticonvulsant) may decrease folate plasma levels. Information on other second-generation anticonvulsants impact on folate levels is limited and cannot be ruled out. Methotrexate, alcohol (in excess), sulfasalazine, cholestyramine, colchicine, colestipol, L-dopa, methylprednisone, NSAIDs (high dose), pancreatic enzymes (pancrelipase, pancratin), pentamidine, pyrimethamine, smoking, triamterene, and trimethoprim may decrease folate plasma levels. Warfarin can produce significant impairment in folate status after a 6 month therapy.

Patient Information

Metafolbic™ is a medical food recommended for use under the supervision of a physician or medical professional.

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

Usual adult dose is one to two tablets daily or as directed by your medical practitioner. **Metafolbic™** is not recommended for use with children under the age of twelve.

How Supplied

Metafolbic™ is available as a round coated, blue colored tablet. Debossed with "LMF" on one side and "6" on the other side.

Bottles of 90 tablets 51991-810-90**.
Use under medical/physician supervision.

**Breckenridge Pharmaceutical, Inc. does not represent these product codes to be actual 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 to 15°-30°C (59°-86°F). See USP Controlled Room Temperature. Protect from moisture and light.

Patents

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

Metafolin® is a trade mark of Merck KGaA, Darmstadt, Germany.

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

Rev. 11/16

PC0377-00