

**L-METHYL-MC- levomefolate calcium, riboflavin, pyridoxine hydrochloride, and cyanocobalamin tablet, coated**  
**Virtus Pharmaceuticals**

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**L-Methyl-MC Tablets**

A medical food for the dietary management of hyperhomocysteinemia.

**Description**

Each round coated blue colored tablet contains:

**Dietary Ingredients :**

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

**Ingredients**

Microcrystalline Cellulose, Pyridoxine HCl, Opadry II Blue #40L10890 (Polydextrose, Hypromellose HPMC 2910, FD&C Blue #1 Aluminum Lake, Triacetin, Titanium Dioxide, Peg 8000). Stearic Acid (Vegetable Source), Croscarmellose Sodium, L-methylfolate Calcium, Riboflavin, Silicon Dioxide, Magnesium Stearate (Vegetable Source), Opadry II Clear #Y-19-7483, (Hypromellose HPMC 2910, Maltodextrin, Peg 400), Cyanocobalamin.

**L-Methyl-MC Tablets** do not contain sugar, lactose, yeast or gluten.

**Indication and Usage**

**L-Methyl-MC Tablets** are indicated for the distinct nutritional requirements of individuals under medical supervision for hyperhomocysteinemia; with particular emphasis for individuals diagnosed with or at risk for mild to moderate: cognitive impairment<sup>1</sup>, vascular dementia<sup>2</sup>, or Alzheimer's disease<sup>3</sup>.

**Precautions**

Folates, when administered as a single agent in doses above 0.1mg daily, may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. The 1 mg of cyanocobalamin contained in **L-Methyl-MC Tablets** has been shown to provide an adequate amount of cyanocobalamin to address this precaution<sup>4</sup>. A safe upper limit of 100 mg per day has been established for the unsupervised medical use of pyridoxine. Consider all sources of pyridoxine supplementation when prescribing **L-Methyl-MC Tablets**.

**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 L-Methylfolate Calcium. 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 **L-Methyl-MC Tablets**. If headaches should occur with the use of **L-Methyl-MC Tablets** consult with

your medical practitioner.

## **Contraindications**

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

## **Drug Interactions**

### **L-Methyl-MC Tablets 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 when prescribing **L-METHYL-MC TABLETS** 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 L-METHYL-MC TABLETS**

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, pancreatin), 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**

**L-Methyl-MC Tablets** is a medical food for use only under medical supervision.

## **Dosage and Administration**

Usual adult dose is one to two tablets daily or as directed by your medical practitioner. L-Methyl-MC Tablets is not recommended for use with children under the age of twelve.

## **How Supplied**

Available as a round coated blue colored tablet. Debossed with "V360" on one side and blank on the other. Commercial product is supplied in bottles of 90 tablets (76439-360-90<sup>1</sup>). Use under medical/physician supervision.

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<sup>1</sup> Virtus Pharmaceuticals, LLC does not represent this product code to be a National Drug Code (NDC) number. Instead, Virtus Pharmaceuticals, LLC has assigned a product code formatted according to standard industry practice to meet the formatting requirements of pharmacy and health insurance computer systems.

## **Storage**

Store at controlled room temperature 15°C to 30°C (59°F to 86°F) (See USP).

## **Patents**

Some or all of the following-patents may apply:

U.S. Patent No. 5,563,126

U.S. Patent No. 5,795,873

U.S. Patent No. 5,997,915

U.S. Patent No. 6,011,040

U.S. Patent No. 6,207,651

U.S. Patent No. 6,254,904

U.S. Patent No. 6,297,224

U.S. Patent No. 6,528,496

and other pending patent applications.

## **References**

<sup>1</sup> Lehmann M, Regland B, Blennow K, and Gottfries CG: Vitamin B12-B6-Folate Treatment Improves Blood-Brain Barrier Function in Patients with Hyperhomocysteinaemia and Mild Cognitive Impairment. *Dementia and Geriatric Cognitive Disorders* 2003;16:145-150.

<sup>2</sup> Nilsson K, Gustafson L, and Hultberg B: Improvement of cognitive functions after cobalamin/folate supplementation in elderly patients with dementia and elevated plasma homocysteine. *International Journal of Geriatric Psychiatry* 2001;16:609-614.

<sup>3</sup> Seshadri S, Beiser A, Selhub J, Jacques PF, Rosenberg IH, D'Agostino RB, Wilson PWF, and Wolf PA: Plasma Homocysteine As A Risk Factor For Dementia And Alzheimer's Disease. *New England Journal of Medicine* 2002:Vol346, No. 7:476-483.

<sup>4</sup> Lederle FA: Oral cobalamin for pernicious anaemia: medicine's best kept secret. *JAMA* 1991;265:94-95.

## **Manufactured for:**

Virtus Pharmaceuticals, LLC

Tampa, FL 33619

PC0296-00

Revised 11/14

## **PRINCIPAL DISPLAY PANEL - 90 Tablet Bottle Label**

**VIRTUS**

**PHARMACEUTICALS**

76439-360-90

**L-METHYL-MC**

**TABLETS**

**R<sub>x</sub>**


**90 Tablets**

Made in the USA

**Description:**  
Each round, coated, blue colored tablet contains:

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

**Ingredients:**  
 Microcrystalline cellulose, Pyridoxine HCl, Opadry II Blue #40 L10890 (Polydextrose, Hypromellose HPMC 2910, FD&C Blue #1 Aluminum Lake, Triacetin, Titanium Dioxide, Peg 8000). Stearic acid (vegetable source), Croscarmellose sodium, L-methylfolate calcium, Riboflavin, Silicon dioxide, Magnesium stearate (vegetable source), Opadry II Clear #Y-19-7483, (Hypromellose HPMC 2910, Maltodextrin, Peg 400), Cyanocobalamin. Sugar, Lactose, Yeast and Gluten Free.  
 See package insert for complete product information.  
**Pharmacist:** L-Methyl MC Tablets is a medical food for use only under medical supervision. Rev. 11/14



76439-360-90

## L-METHYL-MC


TABLETS

**Rx**  
**90 Tablets**

Made in the USA

L-Methyl-MC is not recommended for use in children under the age of twelve. Store at controlled room temperature 15°-30°C (59°-86°F). [See USP]. Protect from light and moisture. Dispense in a light, light-resistant container. If you are pregnant or nursing a baby, please ask a health professional. KEEP THIS OUT OF REACH OF CHILDREN. All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. Call your medical practitioner about side effects. You may report side effects by calling 813-283-1344 or 1-888-848-3593.  
 Manufactured for: Virtus Pharmaceuticals, LLC, Tampa, FL 33619

Lot No: \_\_\_\_\_ Exp. \_\_\_\_\_



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76439-360-90

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PC0285-00

## L-METHYL-MC

levomefolate calcium, riboflavin, pyridoxine hydrochloride, and cyanocobalamin tablet, coated

### Product Information

<b>Product Type</b>	MEDICAL FOOD	<b>Item Code (Source)</b>	NHRIC:76439-360
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Levomefolate Calcium</b> (UNII: A9R10K3F2F) (Levomefolic Acid - UNII:8S95DH25XC)	Levomefolate Calcium	6 mg
<b>Riboflavin</b> (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	5 mg
<b>Pyridoxine Hydrochloride</b> (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1B16Z)	Pyridoxine Hydrochloride	50 mg
<b>Cyanocobalamin</b> (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	1 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>Cellulose, Microcrystalline</b> (UNII: OP1R32D61U)	
<b>Polydextrose</b> (UNII: VH2XOU12IE)	
<b>FD&amp;C Blue No. 1</b> (UNII: H3R47K3TBD)	
<b>Aluminum Oxide</b> (UNII: LMI26O6933)	
<b>Triacetin</b> (UNII: XHX3C3X673)	
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)	
<b>Polyethylene Glycol 8000</b> (UNII: Q662QK8M3B)	
<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)	
<b>Croscarmellose Sodium</b> (UNII: M28OL1HH48)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Magnesium Stearate</b> (UNII: 70097M6I30)	
<b>Maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>Polyethylene Glycol 400</b> (UNII: B697894SGQ)	

**Product Characteristics**

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10 mm
<b>Flavor</b>		<b>Imprint Code</b>	V360
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:76439-360-90	90 in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
MEDICAL FOOD		02/09/2015	

**Labeler** - Virtus Pharmaceuticals (969483143)

Revised: 9/2015

Virtus Pharmaceuticals