

**L-METHYLFOLATE CALCIUM- levomefolate calcium tablet**  
**Westminster Pharmaceuticals, LLC**

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**L-Methylfolate Calcium 7.5 mg Tablets**  
**L-Methylfolate Calcium 15 mg Tablets**

**DESCRIPTION**

L-Methylfolate Calcium Tablets are a medical food for the dietary management of conditions relating to sub-optimal L-methylfolate levels, recommended for use under the supervision of a physician or healthcare provider.

Each **L-Methylfolate Calcium 7.5 mg** tablet contains:

Folate (L-methylfolate	12,750
Calcium 7.5 mg)	mcg DFE

Each **L-Methylfolate Calcium 15 mg** tablet contains:

Folate (L-methylfolate	25,500
Calcium 15 mg)	mcg DFE

**L-Methylfolate Calcium 7.5 mg** Other Ingredients: Microcrystalline Cellulose, Pregelatinized Starch, Hydroxypropyl Methylcellulose, Titanium Dioxide, Silicon Dioxide, Polydextrose, Magnesium Stearate, Triacetin, Polyethylene Glycol, FD&C Blue #1 Aluminum Lake, and FD&C Blue #2 Aluminum Lake.

**L-Methylfolate Calcium 7.5 mg** tablets do not contain sugar, lactose, yeast or gluten.

**L-Methylfolate Calcium 15 mg** Other Ingredients: Microcrystalline Cellulose, Pregelatinized Starch, Hydroxypropyl Methylcellulose, Silicon Dioxide, Polydextrose, Titanium Dioxide, Magnesium Stearate, Triacetin, FD&C Yellow #6 Aluminum Lake, Polyethylene Glycol.

**L-Methylfolate Calcium 15 mg** tablets do not contain sugar, lactose, yeast or gluten.

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

**L-Methylfolate Calcium** 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.**

## **CLINICAL PHARMACOLOGY**

**L-Methylfolate Calcium** is a medical food, which consists of a proprietary biologically active folate, derived from food sources.

## **INDICATIONS AND USAGE**

L-Methylfolate Calcium Tablets are labeled as a medical food for the distinct nutritional requirements of individuals who have or are at risk for hyperhomocysteinemia and other conditions relating to suboptimal L-methylfolate levels.

## **CONTRAINDICATIONS**

L-Methylfolate Calcium is contraindicated in patients with known hypersensitivity to any of the components contained in this product.

### **General**

Folic acid, when administered in daily doses above 0.1 mg, may obscure the detection of B<sub>12</sub> deficiency (specifically, the administration of folic acid may reverse the hematological manifestations of B<sub>12</sub> deficiency, including pernicious anemia, while not addressing the neurological manifestations). 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 Calcium is a medical food<sup>1</sup> for use under the medical supervision of a physician or health-care provider.**

### **Interaction with Drugs**

Before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist. No decrease in effectiveness of drugs has been reported with the use of L-Methylfolate Calcium.

L-Methylfolate Calcium contains folate, which may have interactions with the following:

- Antiepileptic drugs (AED): The AED class including, but not limited to, phenytoin, carbamazepine, primidone, valproic acid, phenobarbital and lamotrigine have been shown to impair folate absorption and increase the metabolism of circulating folate.

Additionally concurrent use of folic acid has been associated with enhanced phenytoin metabolism, lowering the level of this AED in the blood and allowing break through seizures to occur.<sup>4,5,7,10</sup>

- Capecitabine: Folinic acid (5-formyltetrahydrofolate) may increase the toxicity of Capecitabine.<sup>6</sup>
- Dihydrofolate Reductase Inhibitors (DHFRIs): DHFRIs block the conversion of folic acid to its active forms, and lower plasma and red blood cell folate levels. DHFRIs include aminopterin, methotrexate, pyrimethamine, triamterene, and trimethoprim.<sup>7</sup>
- Fluoxetine: Fluoxetine exerts a non-competitive inhibition of the 5-methyltetrahydrofolate active transport in the intestine.<sup>8</sup>
- Isotretinoin: Reduced folate levels have occurred in some patients taking isotretinoin.<sup>9</sup>
- Nonsteroidal Anti-inflammatory Drugs (NSAIDs): NSAIDs have been shown to inhibit some folate dependent enzymes in laboratory experiments NSAIDs include ibuprofen, naproxen, indomethacin and sulindac.<sup>7</sup>
- Oral Contraceptives: Serum folate levels may be depressed by oral contraceptive therapy.<sup>7</sup>
- Methylprednisolone: Reduced serum folate levels have been noted after treatment with methylprednisolone.<sup>7</sup>
- Pancreatic Enzymes: Reduced folate levels have occurred in some patients taking pancreatic extracts.<sup>7</sup>
- Pentamidine: Reduced folate levels have been seen with prolonged intravenous pentamidine.<sup>7</sup>
- Metformin treatment in patients with type 2 diabetes decreases serum folate.<sup>11,12</sup>
- Warfarin can produce significant impairment in folate status after a 6-month therapy.<sup>13</sup>

## **ADVERSE REACTIONS**

Allergic reactions have been reported following the use of oral L-methylfolate Calcium.<sup>14</sup>

**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 7.5 mg (12,750 mcg DFE) to 15 mg (25,500 mcg DFE) given daily with or without food or as directed under medical supervision.

## **HOW SUPPLIED**

**L-Methylfolate Calcium is a medical food for use under the supervision of a physician or healthcare provider.**

**L-Methylfolate Calcium 7.5 mg** is a round light-blue tablet, imprinted with "280" on one side and blank on the other side.

Bottles of 30 Product Code 69367-280-30<sup>1</sup> Use under medical/physician supervision.

Bottles of 90 Product Code 69367-280-09<sup>1</sup> Use under medical/physician supervision.

**L-Methylfolate Calcium 15 mg** is an orange oval-coated tablet, imprinted with "281" on one side and blank on the other side.

Bottles of 90 Product Code 69367-281-09<sup>1</sup> Use under medical/physician supervision.

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1 Westminster Pharmaceuticals, LLC. 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 light and moisture.

## **REFERENCES**

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.
4. Hernandez-Diaz. N Engl J Med. 2000; 343: 1608-14.
5. Morrell M. Curr. 2002; 2(2):31-34.
6. Capecitabine Package Insert; Roche Laboratories, 2000
7. Natural Standard Research Collaboration (NIH). Folate (folic acid) Monograph 2009
8. Amiburu A, et al. J. Physiol. Biochem., 57 (2), 71-80, 2001
9. Chanson A, et al. JEADV 2008, 22:94-100
10. Tatum IV W et al. Arch Intern Med. 2004;164:137-45.
11. Wulffele MG, et al. Journal of Internal Medicine 2003; 254: 455- 463.
12. Desouza C, et al. Drugs 2002; 62(4): 605-16.
13. Sobczyriska-Malefora A et al. Blood Coagul Fibrinolysis 2009 Jun;20(4):297-302
14. Natural Standard Research Collaboration (NIH). Folate (folic acid) Monograph 2009.

**To report a serious adverse event contact: 1-844-221-7294**

### **Manufactured for:**

Westminster Pharmaceuticals , LLC  
Nashville, TN 37217

7357 & 7358  
Rev 08/2021

## **PRINCIPAL DISPLAY PANEL - 15 mg Tablet Bottle Label**

69367-281-09

L-Methylfolate  
Calcium Tablets

15 mg

Do not use this product if the safety seal

under this cap is torn, broken or missing.

Medical Food  
90 Tablets

Westminster  
Pharmaceuticals

**69367-281-09**

**L-Methylfolate Calcium Tablets**

**15 mg**

Medical Food 90 Tablets

WP Westminster Pharmaceuticals

**DESCRIPTION:** L-Methylfolate Calcium Tablets is a medical food for the dietary management of conditions relating to sub-optimal L-methylfolate levels, recommended for use under the supervision of a physician or healthcare provider.

**DOSAGE AND ADMINISTRATION:** The usual adult dose is 15 mg (25,500 mcg DFE) given daily with or without food or as directed under medical supervision.

**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 light and moisture.

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.

**Manufactured for:**  
Westminster Pharmaceuticals, LLC  
Nashville, TN 37217

7357  
Rev 08/2021

**Each L-Methylfolate Calcium 15 mg tablet contains:**  
Folate ..... 25,500 mcg DFE  
(15 mg L-Methylfolate Calcium)

**Other Ingredients:** Microcrystalline Cellulose, Pregelatinized Starch, Hydroxypropyl Methylcellulose, Silicon Dioxide, Polydextrose, Titanium Dioxide, Magnesium Stearate, Triacetin, FD&C Yellow #6 Aluminum Lake, Polyethylene Glycol.

**KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN.**

**To report a serious adverse event contact:**  
1-844-221-7294

N  
3 69367 28109 6

Lot:  
Exp. Date:

### PRINCIPAL DISPLAY PANEL - 7.5 mg Tablet Bottle Label

69367-280-09

L-Methylfolate  
Calcium Tablets

7.5 mg

Do not use this product if the safety seal  
under this cap is torn, broken or missing.

Medical Food  
90 Tablets

Westminster  
Pharmaceuticals

**DESCRIPTION:** L-Methylfolate Calcium Tablets is a medical food for the dietary management of conditions relating to sub-optimal L-methylfolate levels, recommended for use under the supervision of a physician or healthcare provider.

**DOSAGE AND ADMINISTRATION:** The usual adult dose is 7.5 mg (12,750 mcg DFE) to 15 mg (25,500 mcg DFE) given daily with or without food or as directed under medical supervision.

**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 light and moisture.

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.

**Manufactured for:**  
Westminster Pharmaceuticals, LLC      7358  
Nashville, TN 37217      Rev 08/2021

69367-280-09

# L-Methylfolate Calcium Tablets

7.5 mg

Do not use this product if the safety seal under this cap is torn, broken or missing.

**Medical Food      90 Tablets**

**Each L-Methylfolate Calcium 7.5 mg tablet contains:**  
Folate ..... 12,750 mcg DFE (7.5 mg L-Methylfolate Calcium)

**Other Ingredients:** Microcrystalline Cellulose, Pregelatinized Starch, Hydroxypropyl Methylcellulose, Titanium Dioxide, Silicon Dioxide, Polydextrose, Magnesium Stearate, Triacetin, Polyethylene Glycol, FD&C Blue #1 Aluminum Lake, and FD&C Blue #2 Aluminum Lake.

**KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN.**

**To report a serious adverse event contact: 1-844-221-7294**

N 3 69367 28009 9

Lot: \_\_\_\_\_  
Exp. Date: \_\_\_\_\_

## L-METHYLFOLATE CALCIUM

levomefolate calcium tablet

### Product Information

<b>Product Type</b>	MEDICAL FOOD	<b>Item Code (Source)</b>	NHRIC:69367-281
<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	15 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	

### Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	281

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69367-281-09	90 in 1 BOTTLE, PLASTIC		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
MEDICAL FOOD		04/09/2021	08/01/2024

**L-METHYLFOLATE CALCIUM**

levomefolate calcium tablet

**Product Information**

<b>Product Type</b>	MEDICAL FOOD	<b>Item Code (Source)</b>	NHRIC:69367-280
<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	7.5 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	
<b>FD&amp;C BLUE NO. 2 ALUMINUM LAKE</b> (UNII: 4AQJ3LG584)	

**Product Characteristics**

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	280

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69367-280-30	30 in 1 BOTTLE, PLASTIC		
2	NHRIC:69367-280-09	90 in 1 BOTTLE, PLASTIC		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
MEDICAL FOOD		04/09/2021	05/01/2024

**Labeler** - Westminster Pharmaceuticals, LLC (079516651)

Revised: 8/2022

Westminster Pharmaceuticals, LLC