

L-Methylfolate Calcium Tablets, 7.5 mg & 15 mg

DESCRIPTION

L-Methylfolate Calcium Tablets is a medical food dispensed by prescription for the clinical dietary management of the metabolic imbalances associated with depression and schizophrenia. Use under medical supervision.

Each L-Methylfolate Calcium 7.5 mg tablet contains 7.5 mg of L-methylfolate calcium.

Each L-Methylfolate Calcium 15 mg tablet contains 15 mg of L-methylfolate calcium.

L-Methylfolate Calcium Tablets 7.5 mg Dietary Ingredients

Microcrystalline cellulose, dibasic calcium phosphate dihydrate, opadry II blue 85F90748 (polyvinyl alcohol, titanium dioxide [color], PEG 3350, talc and FD&C blue #2 [color]), L-methylfolate calcium, magnesium stearate and colloidal silicon dioxide.

L-Methylfolate Calcium Tablets 15 mg Dietary Ingredients

Microcrystalline cellulose, dibasic calcium phosphate dihydrate, opadry II orange 85F43102, (polyvinyl alcohol, PEG 3350, talc, titanium dioxide [color], FD&C yellow #6 [color], FD&C yellow #5 [color], FD&C red #40 [color] and FD&C blue #2 [color]), L-methylfolate calcium, magnesium stearate and colloidal silicon dioxide.

Medical foods are intended for a patient who has a 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.¹ This product is not an Orange Book product.

L-Methylfolate Calcium Tablets is a medical food dispensed by prescription.

CLINICAL PHARMACOLOGY

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

INDICATIONS AND USAGE

ADJUNCTIVE USE IN MAJOR DEPRESSIVE DISORDER

L-Methylfolate Calcium Tablets is indicated for the distinct nutritional requirements of individuals who have suboptimal folic acid levels in the cerebrospinal fluid, plasma, and/or red blood cells and have major depressive disorder (MDD) with particular emphasis as adjunctive support for individuals who are on an antidepressant.²⁻⁵

ADJUNCTIVE USE IN SCHIZOPHRENIA

L-Methylfolate Calcium Tablets is indicated for the distinct nutritional requirements of individuals who have or are at risk for hyperhomocysteinemia and have schizophrenia who present with negative symptoms and/or cognitive impairment, with particular emphasis as an adjunctive support for individuals who have stabilized on antipsychotics.²

L-Methylfolate Calcium Tablets is indicated regardless of MTHFR C677T polymorphism genotype.⁶

CONTRAINDICATIONS

L-Methylfolate Calcium Tablets 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 0.1mg, may obscure the detection of B₁₂ deficiency (specifically, the administration of folic acid may reverse the hematological manifestations of B₁₂ deficiency, including pernicious anemia, while not addressing the neurological manifestations). L-Methylfolate Calcium Tablets may be less likely than folic acid to mask vitamin B₁₂ deficiency.^{7,8} Folate therapy alone is inadequate for the treatment of a B₁₂ deficiency.

A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed, (although not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of a precipitation of a mixed/manic episode in patients at risk for bipolar disorder. L-Methylfolate Calcium Tablets is not an antidepressant; however, 5-MTHF has been shown to enhance antidepressant effects of known antidepressants.² Caution is recommended in patients with a history of bipolar illness. Patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder since mood elevation in this population is possible.

Patient Information

L-Methylfolate Calcium Tablets is a medical food¹ for use under medical supervision and direction.

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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 Tablets.

L-Methylfolate Calcium Tablets 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 breakthrough seizures to occur.^{9,10,12,15}
- Capecitabine: Folinic acid (5-formyltetrahydrofolate) may increase the toxicity of Capecitabine.¹¹
- Dihydrofolate Reductase Inhibitors (DHFRi): DHFRi block the conversion of folic acid to its active forms, and lower plasma and red blood cell folate levels. DHFRi include aminopterin, methotrexate, pyrimethamine, triamterene, and trimethoprim.¹²
- Fluoxetine: Fluoxetine exerts a noncompetitive inhibition of the 5-methyltetrahydrofolate active transport in the intestine.¹³
- Isotretinoin: Reduced folate levels have occurred in some patients taking isotretinoin.¹⁴
- 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.¹²
- Oral Contraceptives: Serum folate levels may be depressed by oral contraceptive therapy.¹²
- Methylprednisolone: Reduced serum folate levels have been noted after treatment with methylprednisolone.¹²
- Pancreatic Enzymes: Reduced folate levels have occurred in some patients taking pancreatic extracts.¹²
- Pentamidine: Reduced folate levels have been seen with prolonged intravenous pentamidine.¹²
- Metformin treatment in patients with type 2 diabetes decreases serum folate.^{16,17}
- Warfarin can produce significant impairment in folate status after a 6-month therapy.¹⁸

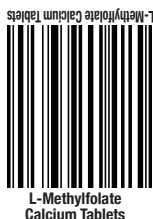
ADVERSE REACTIONS

Allergic reactions have been reported following the use of oral L-Methylfolate Calcium Tablets.

Call your medical practitioner about side effects. You may report side effects by calling +1-855-204-1431.

DOSAGE AND ADMINISTRATION

The usual adult dose is 7.5 mg to 15 mg given daily with or without food or as directed under medical supervision.



HOW SUPPLIED

L-Methylfolate Calcium Tablets is a medical food dispensed by prescription.

7.5 mg

Bottle of 30 - Product Code # 70954-559-20¹

Bottle of 90 - Product Code # 70954-559-10¹

Use under medical/physician supervision.

A light blue colored, round, coated tablet debossed with N559 on one side and plain on other side.

15 mg

Bottle of 90 - Product Code # 70954-560-10¹

Use under medical/physician supervision.

An orange colored, oval, coated tablet debossed with N560 on one side and plain on other side.

¹ Novitium Pharma 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 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from heat, light and moisture.

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