

Enlyte® D

{6 mg LMTHF, 25mg B6, 2mg B12, 5000IU Vit. D}

MEDICAL FOOD

64661-750-90 [90 Tablets]

Certified Gluten Free

Dye Free

Bovine Free

Soy Free

Sugar Free

Casein Free

Lactose Free

Yeast Free

Glucose Free

Fish Free

Shellfish Free

DESCRIPTION

Enlyte® D is a medical food to be used under medical supervision that has been specifically formulated for patients with methylenetetrahydrofolate reductase (MTHFR) genotypes and/or genotypes in Vitamin D transport and other B-Vitamin polymorphisms that may contribute to hyperhomocysteinemia and/or Vitamin D deficiency. **Enlyte® D** provides patients special, medically-determined nutrient requirements including L-methylfolate, Vitamin D, and other B vitamin coenzymes and mineral co-factors in amounts that cannot be achieved by the modification of the normal diet alone.

INGREDIENTS: *Each tablet contains the following ingredients:*

<i>L-methylfolate magnesium</i>	6 mg
<i>Methylcobalamin</i>	2 mg
<i>Pyridoxal-5'-Phosphate</i>	25 mg
<i>Vitamin D₃</i>	5000 IU
<i>Zinc Ascorbate</i>	25 mg
<i>Magnesium-L-Threonate</i>	25 mg

Dietary Ingredients:

Microcrystalline Cellulose, Pyridoxal-5'-Phosphate, Zinc Ascorbate, Magnesium L-Threonate, Pregeletanized starch, Crocarmellose sodium, Vitamin D₃, L-methylfolate Magnesium, Talc, Magnesium Stearate, Titanium Dioxide, Methylcobalamin.

Contains.

Enlyte® D tablets DO NOT contain gluten, dyes, bovine, soy, sugar, casein, lactose, yeast, glucose, fish, or shellfish.

Medical foods are intended for patients who have a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who have other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone.¹ **This is not an Orange Book Product.**

L-methylfolate is the primary biologically active diastereomer of folate. It is the primary form of folate in circulation, and is also the form transported across cell membranes – particularly across the blood brain barrier and into peripheral tissues. In the cell, L-methylfolate is used in the re-methylation of homocysteine to form methionine and

tetrahydrofolate (THF). About 70% of food folate and cellular folate is comprised of L-methylfolate. Folic acid, the synthetic form of folate, must undergo enzymatic reduction by methylenetetrahydrofolate reductase (MTHFR) to be biologically active. Genetic polymorphisms of MTHFR result in a cell's inability to convert folic acid to L-methylfolate.² The inability for a cell to reduce homocysteine to methionine may result in hyperhomocysteinemia. Vitamin D deficiencies have been shown to correlate with three specific genetic variants.³ The genes in question (DHCR7/NADSYN1, CYP2R1 and GC) were involved in cholesterol synthesis, hydroxylation, and Vitamin D transport.⁴ **Enlyte® D** is specifically formulated to help patients meet medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of diet alone.

PHARMACOLOGY

FOLATE has been reported to enhance synthesis and/or regeneration of tetrahydrobiopterin (BH₄), which is an essential cofactor in the biosynthesis of monoamine neurotransmitters serotonin, dopamine and norepinephrine.^{5,6,7} **Enlyte® D** contains L-methylfolate magnesium, a folate salt that is twice as soluble as the calcium form found in other folate preparations. L-methylfolate is converted into functional, metabolically active coenzyme forms for use in the body, and supplies the active folate substrate, THF for use in transformylation and methylation biochemistry. It has been reported that MTHFR polymorphism may contribute to the incidence and severity of substance addiction and dependency.⁸ It has also been shown that patients with hyperhomocysteinemia associated with the C677T variant of the MTHFR gene have a higher frequency of migraines.⁹

VITAMIN D is a fat-soluble vitamin. Unlike water-soluble vitamins, fat-soluble vitamins dissolve in fat and are stored in body tissues. Vitamin D is able to cross the blood-brain barrier. Vitamin D regulates the expression of tyrosine hydroxylase, the rate limiting enzyme in the biosynthesis of dopamine, norepinephrine, and epinephrine.¹⁰ Vitamin D promotes the survival of monoaminergic neurons through upregulation of glial cell line-derived neurotrophic factor. Reports have also shown that Vitamin D may be involved in neurodevelopment and may have a neuroprotective effect on dopaminergic pathways in the adult brain.¹¹ Vitamin D deficiencies have also been shown to be associated with psychiatric illnesses, particularly depression.¹² Low Vitamin D concentrations have been associated with impairments in cognitive functions such as memory and orientation, executive function impairments, and Alzheimer's disease.¹³

VITAMIN B₁₂ is required for the conversion of homocysteine to methionine, a reaction in which the methyl group of L-methylfolate is donated to re-methylate homocysteine. Homocysteine has been reported to stimulate or alter transcription factors involved in inflammation, with an important ancillary consequence of BH₄ depletion.

VITAMIN B₆ plays a critical role in the generation of glutathione (from cysteine) from homocysteine, as well as for the recycle of other B-vitamins. The aromatic amino acid decarboxylase considered to decarboxylate both dihydroxyphenylalanine (DOPA) and 5-hydroxytryptophan (5-HTP) requires pyridoxal-5'-phosphate as coenzyme.

MAGNESIUM plays an important role in biochemical reactions all over the body. It is involved in many cell transport activities, in addition to helping cells make energy aerobically or anaerobically. The combination of high doses of Vitamin D and magnesium supplementation improves magnesium absorption and utility.¹⁴ Magnesium has been reported to help modulate the presynaptic transmitters release, the agonist induced response at the level of some receptors, and also several ion-gated channels.¹⁵

ZINC is one of the most abundant trace minerals in the brain.¹⁶ It has been reported that Zinc activates the hippocampal neurogenesis through the upregulation of brain derived neurotrophic factor (BDNF).¹⁷ Zinc has been reported to help modulate the presynaptic transmitters release, the agonist induced response at the level of some receptors, and also several ion-gated channels.¹⁸

INDICATIONS AND USAGE

Enlyte® D is indicated for patients with distinct nutritional requirements for the dietary management of certain metabolic processes and IEMs (Inborn Errors of Metabolism) identified with hyperhomocysteinemia that contribute to major depressive disorder;^{19, 20, 21} pain, tingling, and sensation related to diabetic peripheral neuropathy;²² dementia, cognitive dysfunction, and Alzheimer's disease;²³ addiction and or abuse abatement;^{24, 25, 26} early and end stage renal disease; migraine with or without aura;²⁷ and age related macular degeneration.²⁸

PRECAUTIONS

Caution is recommended in patients with a family history of bipolar illness. Mood elevation is possible in this population.

Patients undergoing cancer treatment should consult their licensed medical practitioner for advice.

Folate, when administered in daily doses above 0.1mg, may obscure the detection of vitamin B₁₂ deficiency (specifically, the administration of folic acid may reverse the hematological manifestations of vitamin B₁₂ deficiency, including pernicious anemia, while not addressing the neurological manifestations). L-methylfolate may be less likely than folic acid to mask vitamin B₁₂ deficiency.²⁹ Folate therapy alone is inadequate for the treatment of a vitamin B₁₂ deficiency.

PATIENT INFORMATION:

Enlyte® D is a medical food dispensed under medical supervision and direction.

ADVERSE REACTIONS:

Allergic reactions have been reported following the use of oral and parenteral folate.³⁰ Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, and the feeling of swelling of the entire body have been associated with methylcobalamin.³¹ Allergic reactions, acne, skin reactions, photosensitivity, nausea, vomiting, abdominal pain, loss of

appetite, paresthesia, somnolence, nausea, and headaches have been associated with pyridoxal-5'-phosphate.³² Call your licensed medical practitioner about side effects.

DRUG INTERACTIONS:

This product is contraindicated in patients with a known hypersensitivity to any of the articles contained in this product. This product is contraindicated for individuals with conditions for which any of the ingredients are contraindicated.

Talk to your licensed medical practitioner, healthcare practitioner, personal physician, and/or pharmacist before taking or using any prescription, over-the-counter medicines, or herbal/health supplements alongside this product.

DOSAGE AND ADMINISTRATION:

The usual adult dose may be taken as one (1) tablet daily, or as directed by a licensed medical practitioner.

HOW SUPPLIED:

Enlyte® D tablets are available as a white/off-white speckled tablet with the imprint "750" and are supplied in bottles of 90 tablets and are dispensed under medical supervision. Bottle of 90† Product Code 64661-750-90* (90 ct. bottle / 90 Tablets).

*Jaymac Pharmaceuticals, LLC. does not represent this product code to actual National Drug Codes (NDCs). NDC format codes are Product Codes adjusted according to standard industry practice to meet the formatting requirements of pharmacy and health insurance companies.

STORAGE:

Store at Controlled Room Temperature 15°-30° C (59°-86°F). [See USP]. Protect from light and moisture. Dispense in a tight, light-resistant container.

Call your medical practitioner about side effects. You may report side effects by calling (866) 280-5961.

KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN.

MANUFACTURED FOR:
JAYMAC PHARMACEUTICALS, LLC.

Sunset, Louisiana
www.enlyterx.com

MADE IN USA

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Patent Pending

TRADEMARKS: *Enlyte®* is a trademark of Jaymac Pharmaceuticals, LLC. (Sunset, Louisiana).

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