

ENL Softgel

{1 mg. PteGlu CR, 2.2mg. F-THF, 7mg. Me-THF-Mg. 12.5mg. FeGC} MEDICAL FOOD
64661082251 [Multiphasic Softgel]
Certified Gluten Free

DESCRIPTION: ENL Softgel is a medical food to be used under medical supervision that has been specifically formulated for patients with methylenetetrahydrofolate reductase (MTHFR) genotypes and/or other B-Vitamin polymorphisms or folate deficiency that may contribute to hyperhomocysteinemia. ENL Softgel provides patients special, medically-determined nutrient requirements including L-methylfolate, Omega 3s, 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:

L-Methylfolate.....	7mg
Folinic Acid.....	2.2mg
Citrate Folic Acid.....	1 mg
Phospholipid-Omega3s.....	20mg
Ferrous Glycinate Cysteinate.....	12.5mg
Magnesium Ascorbate.....	24mg
Zinc Ascorbate.....	1mg
L-Threonine Acid Magnesium.....	1mg
Vitamin B1Thiamine Pyrophosphate.....	25mcg
Vitamin B2 FAD.....	25mcg
Vitamin B3 NADH.....	25mcg
Vitamin B6 Pyridoxal 5' Phosphate.....	25mcg
Vitamin B12 Adenosylcobalamin.....	25mcg
Vitamin B12 Methylcobalamin.....	25mcg

Excipients: Olive Oil, Gelatin, Purified Water, Yellow Beeswax, Natural Creamy Orange Flavour, Sunflower Lecithin, Annatto, Bioperine, Trimethylglycine, and Ubidecarenone

ENL Softgel DOES NOT CONTAIN artificial dyes, artificial flavours/sweeteners and gluten. ENL Softgel is third-party certified gluten free and contains less than 5000 ppm alcohol

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. **† 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 membranes – particularly across the blood brain barrier – 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 ENL Softgel 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.^{4,5,6} ENL Softgel 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 transmethylation and methylation biochemistry. It has been reported that MTHFR polymorphism may contribute to the incidence and severity of substance addiction and dependency.⁷ It has also been shown that patients with hyperhomocysteinemia associated with the C677T variant of the MTHFR gene have a higher frequency of migraines.⁸

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.⁹ 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.¹⁰

ZINC is one of the most abundant trace minerals in the brain.¹¹ It has been reported that Zinc activates the hippocampal neurogenesis through the upregulation of brain derived neurotrophic factor (BDNF).¹² 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.¹³

INDICATIONS AND USAGE : ENL Soft Gel is indicated for patients with distinct nutritional requirements for the dietary management of certain metabolic processes identified with hyperhomocysteinemia that contribute to major depressive disorder;^{14,15,16} pain, tingling, and sensation related to diabetic peripheral neuropathy;¹⁷ dementia, cognitive dysfunction, and Alzheimer's disease;¹⁸ addiction and/or abuse abatement;^{19,20,21} early and end stage renal disease; migraine with or without aura;²² ADHD, and age related macular degeneration.²³

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.²⁴ Folate therapy alone is inadequate for the treatment of a vitamin B12 deficiency.

PATIENT INFORMATION: ENL Softgel 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.²⁵ Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, and the feeling of swelling of the entire body have been associated with methylcobalamin.²⁶ 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.²⁷ 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) softgel daily, or as directed by a licensed medical practitioner. No age restriction.

HOW SUPPLIED: ENL Softgel tablets are available as a annatto colored softgel with the imprint "ENL" and are supplied in bottles of 30 soft gel and are dispensed under medical supervision. Bottle of 30† Product Code 64661082251

*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.
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Patent Pending

