ADVERSE REACTIONS: Allergic reactions have been reported following the use of oral folate. Mild transient diarrhea, itching, transitory exanthema and the feeling of swelling of the entire body has been associated with B_{12}.

INDICATIONS: CLINICAL DIETARY MANAGEMENT OF MAJOR DEPRESSIVE DISORDER.
EnLyte® is formulated to meet the distinctive nutritional requirement of individuals who have suboptimal L-methylfolate levels in the cerebrospinal fluid, plasma, and/or red blood cells and have major depressive disorder (MDD).

DOSAGE AND ADMINISTRATION: The usual dose is one (1) **EnLyte®** softgel capsule given daily with or without food, or as directed under medical supervision. No age restrictions.

HOW SUPPLIED: EnLyte® Bottle of 30 Product Code # 64661-711-30*. **EnLyte®** is an oval, brownish orange softgel capsule with imprint ENL.

**JAYMAC 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.*

REGULATORY: 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. **This product is not an Orange Book product.**

PATIENT INFORMATION: EnLyte® is a medical food for use under medical supervision.

KEEP THIS OUT OF THE REACH OF CHILDREN. Do not exceed the recommended dose.

STORAGE: Store at controlled room temperature 15°C to 30°C (59°F to 86°F) (See USP). Protect from heat, light and moisture. **(Tamper Evident: Do not use if seal is broken or missing.)**

PATENTS: *Patent applications pending.*

MANUFACTURED FOR:
JAYMAC Pharmaceuticals LLC, 2085 I-49 S. Service Rd Sunset, LA 70584
MANUFACTURED AND/OR PACKAGED IN USA/INDIA

Nov 8, 2023 (V9)

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64661-**711**-30* *USE UNDER MEDICAL SUPERVISION*

EnLyte®

with DeltaFolate™

(L-methylfolate Mg/Folinic Acid/Folic Acid)

JAYMAC Pharmaceuticals, LLC

SOFTGELS (30ct BOTTLE)

Medical Food

DESCRIPTION: EnLyte® is a medical food for use ***only*** under medical supervision to assist MTHFR SNP (IEMs) and methylation coenzyme cofactor deficiency patients in the clinical dietary management of depression and is specially formulated to meet the distinctive nutritional requirements of these patients.

Each EnLyte® softgel capsule contains:
50 mcg adenosylcobalamin (vitamin B_{12}) and 15 mg DFE of reduced folates (from 7 mg l-methylfolate magnesium, 2.5 mg folinic acid and 1 mg folic acid).
*A recent study[+] suggested that **EnLyte®** was effective in lowering homocysteine levels in patients that are positive for MTHFR (methylenetetrahydrofolate reductase polymorphism).*

[+] *ClinicalTrials.gov identifier: NCT02709668, Correlation of Clinical Response With Homocysteine Reduction During Therapy With Reduced B Vitamins in Patients with MDD Who Are Positive for MTHFR C677T or A1298C Polymorphism*

INGREDIENTS: Olive oil, gelatin, glycerin, magnesium ascorbate, Sharp-PS® Gold (phosphatidylserine-DHA complex), yellow beeswax, purified water, sodium citrate, l-methylfolate magnesium, sunflower lecithin, folinic acid, citric acid, annatto extract, elemental iron (from ferrous glycine cysteinate), folic acid, zinc ascorbate, magnesium l-threonate, natural orange flavor, piperine, CoQ10 (ubidecarenone), betaine, vitamin B_{12} (adenosylcobalamin), FAD (flavin adenine dinucleotide), NADH (nicotinamide adenosine dinucleotide hydride), vitamin B_6 (pyridoxal 5′phosphate), vitamin B_1 (thiamine pyrophosphate).

CONTAINS FISH/KRILL/SOY. *No artificial colorants. No dairy, wheat, sugar or egg.*

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

PRECAUTIONS: GENERAL: Folic acid, including reduced forms such as folinic acid, in daily doses above 0.1 mg may obscure the detection of B_{12} deficiency specifically, the administration of folic acid may reverse the hematological manifestations of B_{12} deficiency, including pernicious anemia, while not addressing the neurological issues. Folate therapy alone is inadequate for the treatment of a B_{12} deficiency and must be administered under the supervision of a licensed medical practitioner.