

**ENL- leucovorin, levomefolate magnesium, ferrous cysteine glycinate, 1,2-docosahexanoyl-sn-glycerol-3-phosphoserine calcium, 1,2-icosapentoyl-sn-glycerol-3-phosphoserine calcium, phosphatidyl serine, pyridoxal 5-phosphate, flavin adenine dinucleotide, nadh, cobamamide, cocarboxylase (thiamine pyrophosphate), magnesium ascorbate, zinc ascorbate, magnesium l-threonate and betaine capsule, liquid filled**  
**Jaymac Pharma**

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**ENL™ with DeltaFolate™ plus adenosylcobalamin**

**ENL™**

with DeltaFolate™ plus adenosylcobalamin

**[50 mg CBI] [15 mg DFE Folate]**

**JAYMAC Pharmaceuticals, LLC**

Softgels (30ct bottle)

**Medical Food** For Therapeutic Use

## **Description**

**ENL™** is a medical food for use under medical supervision to assist MTHFR patients in the clinical dietary management of depression and is specially formulated to meet the distinctive nutritional requirement for these patients.

Each **ENL™** capsule contains 15 mg DFE of reduced folates from DeltaFolate™ plus adenosylcobalamin.

*A recent study<sup>+</sup> suggested that EnLyte® was effective in lowering homocystine levels in patients that are positive for MTHFR (methylenetetrahydrofolate reductase polymorphism).*

*<sup>+</sup>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.*

**OTHER INGREDIENTS:** Annatto [colorant], 500 mcg betaine (trimethylglycine), at least 5.5 mg citrates (at least 1.83 mg citric acid, at least 3.67 mg sodium citrates), 25 mcg flavin adenine dinucleotide (reduced vitamin B<sub>2</sub>), cysteinated ferrous chelate (1.5 mg elemental iron), gelatin (bovine), glycerine, 1 mg magnesium l-threonate, 25 mcg nicotinamide adenine dinucleotide hydride (reduced vitamin B<sub>3</sub>), piperine, plant lipids (sunflower), purified water, 25 mcg pyridoxal 5' phosphate (reduced vitamin B<sub>6</sub>), 25 mcg thiamine pyrophosphate (reduced vitamin B<sub>1</sub>), ubidecarenone, yellow beeswax. [Coenzyme B<sub>12</sub> is the primary form most found in mammalian liver. <sup>2</sup>Vitamer of B<sub>12</sub> cofactor, l-methylfolate. <sup>3</sup>Pure amino acid, cysteinated iron chelate. <sup>4</sup> 30% daily value (DV) of VITAMIN C, and 10% DV IRON for geriatrics. <sup>5</sup> Contains at least 12 mg phosphatidylserine (PS)- of which approximately 6.4 mg as PS-DHA-Ca, and less than 1% EPA (<800 mcg PS-EPA-Ca).]

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

## **INDICATIONS:**

### **CLINICAL DIETARY MANAGEMENT OF MAJOR DEPRESSIVE DISORDER**

## **ADVERSE REACTIONS:**

Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, feeling of swelling of entire body may occur with administration of vitamin B<sub>12</sub>. Allergic sensitization has been reported following both oral and parenteral administration of vitamin B<sub>9</sub>.

## **PRECAUTIONS:**

0.1 mg or more of vitamin B<sub>9</sub> daily may obscure pernicious anemia in that the hematological remission may occur while neurological manifestations remain progressive. Exclusive use of vitamin B<sub>9</sub> in treating vitamin B<sub>12</sub>-deficient macrocytic anemia could result in progressive and irreversible neurological damage. Specifically, vitamin B<sub>12</sub> deficiency allowed to progress over 3 months may produce permanent degenerative lesions of the spinal cord - as observed when vitamin B<sub>9</sub> therapy is used as the only hematopoietic agent. Doses of vitamin B<sub>12</sub> exceeding 10 mcg daily may produce hematologic response in patients with vitamin B<sub>9</sub> deficiency. Indiscriminate administration may mask the true diagnosis. *A dietary deficiency of only vitamin B<sub>12</sub> is rare; multiple vitamin deficiency is expected in any dietary deficiency. No single regimen fits all cases, and the status of the patient observed in follow-up is the final criterion for adequacy of therapy.*

## **DOSAGE AND ADMINISTRATION:**

The adult dose is one capsule daily *preferably* on an empty stomach.

**Call your medical practitioner about side effects. You may report side effects by calling 337.662-5962.**

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

**Do not exceed the recommended dose.**

## **HOW SUPPLIED:**

Oval, brownish-orange softgel capsule with imprint **082**.

## **STORAGE:**

**STORAGE:** Store at 20°-25° C (68°-77° F)

**(Tamper Evident: Do not use if seal is broken or missing.)**

JAYMAC Pharmaceuticals, LLC, Sunset, LA 70584

MANUFACTURED AND/OR PACKAGED IN USA/CANADA

label

**INDICATIONS AND USAGE:** CLINICAL DIETARY MANAGEMENT OF MAJOR DEPRESSIVE DISORDER  
ENL 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.  
**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:** ENL is a medical food for use under medical supervision.  
**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 Vitamin B<sub>12</sub>.  
**RECOMMENDED USE:** The usual dose is one (1) ENL capsule given daily with or without food, or as directed under medical supervision. No age restrictions.  
**HOW SUPPLIED:** ENL Bottle of 30 Product Code # 64661-082-25\*. Each ENL reddish brown oval softgel is imprinted with "082".  
\*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.  
**STORAGE:** Store at controlled room temperature 15°C to 30°C (59°F to 86°F) (See USP). Protect from heat, light and moisture.  
**PATENTS:** US Patent No 7,935,365; and other patent applications pending.  
Manufactured for Jaymac Pharmaceuticals LLC., 2085 I-495, Service Rd, Sunset, LA | MADE IN CANADA  
Jan 16 2024 v16

64661-082-25\*

NOT A PRESCRIPTION DRUG\*

**DESCRIPTION:** ENL is a medical food for use under medical supervision to assist patients with MTHFR polymorphisms and other B-vitamin polymorphisms or "1EMs" in the clinical dietary management of depression and is specially formulated to meet the distinctive nutritional requirements for these patients.  
**Each ENL capsule contains:** 15 mg DFE of reduced folates (from 7mg LevoMefolic Acid [L-methylfolate Magnesium, CAS# 1429498-11-2] and ~3.5mg Levoleucovorin [folic acid]) plus 50 mcg adenosylcobalamin (vitamin B<sub>12</sub>).  
A recent study\* suggested that the ingredients in ENL are effective in lowering homocysteine levels in MDD patients that are positive for MTHFR (methyltetrahydrofolate 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 C67T or A1298C Polymorphism.

**INGREDIENTS:** Olive oil, gelatin, magnesium ascorbate, Sharp-PS® Gold (phosphatidylserine-DHA complex), yellow beeswax, purified water, sodium citrate, l-methylfolate magnesium, sunflower lecithin, folic acid, citric acid, annatto extract, elemental iron<sup>1</sup> (from ferrous glycine cysteinate), zinc ascorbate, magnesium l-threonate, natural orange flavor, piperine, CoQ10 (ubidecarenone), betaine, vitamin B<sub>12</sub> (adenosylcobalamin), FAD (flavin adenine dinucleotide), NADH (nicotinamide adenosine dinucleotide hydride), vitamin B<sub>6</sub> (pyridoxal 5' phosphate), vitamin B<sub>1</sub> (thiamine pyrophosphate).  
<sup>1</sup> Pure amino acid, cysteinated iron chelate as AminoFerro® under exclusive license by Vivo Pharmaceuticals, Canada, U.S. Patent #7341708.

**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:** Folic acid, when administered in daily doses above 0.1mg, 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 issues. Folate therapy alone is inadequate for the treatment of a B<sub>12</sub> deficiency.




**SOFTGELS (30ct BOTTLE)**

**Medical Food**

Lot: Exp:



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**ENL**

leucovorin, levomefolate magnesium, ferrous cysteine glycinate, 1,2-docosahexanoyl-sn-glycero-3-phosphoserine calcium, 1,2-icosapentoyl-sn-glycero-3-phosphoserine calcium, phosphatidyl serine, pyridoxal 5-phosphate, flavin adenine dinucleotide, nadh, cobamamide, cocarboxylase (thiamine pyrophosphate), magnesium ascorbate, zinc ascorbate, magnesium l-threonate and betaine capsule, liquid filled

**Product Information**

<b>Product Type</b>	MEDICAL FOOD	<b>Item Code (Source)</b>	NHRIC:64661-082
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>LEUCOVORIN</b> (UNII: Q573I9DVLP) (LEUCOVORIN - UNII:Q573I9DVLP)	LEUCOVORIN	3.5 mg
<b>LEVOMEFOLATE MAGNESIUM</b> (UNII: 1VZZ62R081) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	7 mg
<b>FERROUS CYSTEINE GLYCINATE</b> (UNII: 8B40P7RK5N) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CYSTEINE GLYCINATE	13.6 mg
<b>1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM</b> (UNII: 6WJM73T46K) (1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE - UNII:DVY071LF1W)	1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM	6.4 mg
<b>1,2-ICOSAPENTOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM</b> (UNII: 9ABD9DRK7B) (1,2-ICOSAPENTOYL-SN-GLYCERO-3-PHOSPHOSERINE - UNII:C3019D8IIA)	1,2-ICOSAPENTOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM	800 ug
<b>PHOSPHATIDYL SERINE</b> (UNII: 394XK0IH40) (PHOSPHATIDYL SERINE - UNII:394XK0IH40)	PHOSPHATIDYL SERINE	12 mg
<b>PYRIDOXAL PHOSPHATE ANHYDROUS</b> (UNII: F06SGE49M6) (PYRIDOXAL PHOSPHATE ANHYDROUS - UNII:F06SGE49M6)	PYRIDOXAL PHOSPHATE ANHYDROUS	25 ug
<b>FLAVIN ADENINE DINUCLEOTIDE</b> (UNII: ZC44YT18KK) (FLAVIN ADENINE DINUCLEOTIDE - UNII:ZC44YT18KK)	FLAVIN ADENINE DINUCLEOTIDE	25 ug

<b>NADH</b> (UNII: 4J24DQ0916) (NADH - UNII:4J24DQ0916)	NADH	25 ug
<b>COBAMAMIDE</b> (UNII: FOR1QK73KB) (COBAMAMIDE - UNII:FOR1QK73KB)	COBAMAMIDE	50 ug
<b>COCARBOXYLASE</b> (UNII: Q57971654Y) (COCARBOXYLASE - UNII:Q57971654Y)	COCARBOXYLASE	25 ug
<b>MAGNESIUM ASCORBATE</b> (UNII: 0N1G678593) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	MAGNESIUM ASCORBATE	24 mg
<b>ZINC ASCORBATE</b> (UNII: 9TI35313XW) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ZINC ASCORBATE	1 mg
<b>MAGNESIUM L-THREONATE</b> (UNII: 1Y26ZZ00TM) (THREONIC ACID, L- - UNII:75B0PMW2JF)	MAGNESIUM L-THREONATE	1 mg
<b>BETAINE</b> (UNII: 3SCV180C9W) (BETAINE - UNII:3SCV180C9W)	BETAINE	500 ug
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1.83 mg
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR) (SODIUM CATION - UNII:LYR4MONH37)	SODIUM CITRATE	3.67 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ANNATTO</b> (UNII: 6PQP1V1B6O)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>PIPERINE</b> (UNII: U71XL721QK)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>UBIDECARENONE</b> (UNII: EJ27X76M46)	
<b>YELLOW WAX</b> (UNII: 2ZA36HOS2V)	

### Product Characteristics

<b>Color</b>	BROWN (annatto)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	14mm
<b>Flavor</b>	ORANGE (creamy orange)	<b>Imprint Code</b>	082
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:64661-082-25	30 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
medical food		01/03/2022	

**Labeler** - Jaymac Pharma (830767260)

**Registrant** - Jaymac Pharma (830767260)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Viva Pharmaceuticals INC		253288898	manufacture

Revised: 1/2024

Jaymac Pharma