

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

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⁺ suggested that EnLyte® was effective in lowering homocystine 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.

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 B₂), cysteinated ferrous chelate (1.5 mg elemental iron), gelatin (bovine), glycerine, 1 mg magnesium l-threonate, 25 mcg nicotinamide adenine dinucleotide hydride (reduced vitamin B₃), piperine, plant lipids (sunflower), purified water, 25 mcg pyridoxal 5' phosphate (reduced vitamin B₆), 25 mcg thiamine pyrophosphate (reduced vitamin B₁), ubidecarenone, yellow beeswax. [Coenzyme B₁₂ is the primary form most found in mammalian liver. ²Vitamer of B₁₂ cofactor, l-methylfolate. ³Pure amino acid, cysteinated iron chelate. ⁴ 30% daily value (DV) of VITAMIN C, and 10% DV IRON for geriatrics. ⁵ 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 B₁₂. Allergic sensitization has been reported following both oral and parenteral administration of vitamin B₉.

PRECAUTIONS:

0.1 mg or more of vitamin B₉ daily may obscure pernicious anemia in that the hematological remission may occur while neurological manifestations remain progressive. Exclusive use of vitamin B₉ in treating vitamin B₁₂-deficient macrocytic anemia could result in progressive and irreversible neurological damage. Specifically, vitamin B₁₂ deficiency allowed to progress over 3 months may produce permanent degenerative lesions of the spinal cord - as observed when vitamin B₉ therapy is used as the only hematopoietic agent. Doses of vitamin B₁₂ exceeding 10 mcg daily may produce hematologic response in patients with vitamin B₉ deficiency. Indiscriminate administration may mask the true diagnosis. *A dietary deficiency of only vitamin B₁₂ 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

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 suggested that the ingredients in ENL™ are effective in lowering homocysteine levels in MDD patients that are positive for MTHFR (methylentetrahydrofolate 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 G677T or A1298C Polymorphism.*

INGREDIENTS: 7mg LevoMefolic Acid (L-methylfolate Magnesium, CAS# 1429498-11-2), ~3.5mg Levoleucovorin (folic acid), 50mg adenosylcobalamin.

ALSO CONTAINS: 24mg l-ascorbate magnesium, 1mg l-ascorbate zinc, l-threonate magnesium, thiamine pyrophosphate, flavin adenine dinucleotide, nicotinamide adenosine dinucleotide hydride, pyridoxal 5' phosphate, 20mg phospholipids, 1.5 mg elemental iron† (Ferrous Glycine Cysteinate).
† Pure amino acid, cysteinated iron chelate as AminoFer™ under exclusive license by Viva Pharmaceuticals, Canada, U.S. Patent #7341708.

Excipients: annatto, betaine, citrates, gelatin, glycerin, olive oil, purified water, yellow beeswax, natural orange flavor, sunflower lecithin, piperine, ubiquinol, and others.

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

CONTRAINDICATIONS: ENL™ is contraindicated in patients with known hypersensitivity to any of the components contained in this product.

PRECAUTIONS: 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 issues. Folate therapy alone is inadequate for the treatment of a B₁₂ deficiency.

64661-082-25* NOT A PRESCRIPTION DRUG*



ADVANCED FOLATE SUPPLEMENT



SOFTGELS (30ct BOTTLE)

Medical Food

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 methylcobalamin.

RECOMMENDED USE: The usual dose is one 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 By Viva Pharmaceutical Inc. for Jaymac Pharmaceuticals LLC. | Rev. Oct 2022 v12



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Lot:
Exp:

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

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEUCOVORIN (UNII: Q573I9DVLP) (LEUCOVORIN - UNII:Q573I9DVLP)	LEUCOVORIN	3.5 mg
LEVOMEFOLATE MAGNESIUM (UNII: 1VZZ62R081) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	7 mg
FERROUS CYSTEINE GLYCINATE (UNII: 8B40P7RK5N) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CYSTEINE GLYCINATE	13.6 mg
1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM (UNII: 6WJM73T46K) (1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE - UNII:DVY07ILF1W)	1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM	6.4 mg
1,2-ICOSAPENTOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM (UNII: 9ABD9DRK7B) (1,2-ICOSAPENTOYL-SN-GLYCERO-3-PHOSPHOSERINE - UNII:C3019D8IIA)	1,2-ICOSAPENTOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM	800 ug
PHOSPHATIDYL SERINE (UNII: 394XK0IH40) (PHOSPHATIDYL SERINE - UNII:394XK0IH40)	PHOSPHATIDYL SERINE	12 mg
PYRIDOXAL PHOSPHATE ANHYDROUS (UNII: F06SGE49M6) (PYRIDOXAL PHOSPHATE ANHYDROUS - UNII:F06SGE49M6)	PYRIDOXAL PHOSPHATE ANHYDROUS	25 ug
FLAVIN ADENINE DINUCLEOTIDE (UNII: ZC44YT18KK) (FLAVIN ADENINE DINUCLEOTIDE - UNII:ZC44YT18KK)	FLAVIN ADENINE DINUCLEOTIDE	25 ug
NADH (UNII: 4J24DQ0916) (NADH - UNII:4J24DQ0916)	NADH	25 ug

COBAMAMIDE (UNII: F0R1QK73KB) (COBAMAMIDE - UNII:F0R1QK73KB)	COBAMAMIDE	50 ug
COCARBOXYLASE (UNII: Q57971654Y) (COCARBOXYLASE - UNII:Q57971654Y)	COCARBOXYLASE	25 ug
MAGNESIUM ASCORBATE (UNII: 0N1G678593) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	MAGNESIUM ASCORBATE	24 mg
ZINC ASCORBATE (UNII: 9TI35313XW) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ZINC ASCORBATE	1 mg
MAGNESIUM L-THREONATE (UNII: 1Y26ZZ00TM) (THREONIC ACID, L- - UNII:75B0PMW2JF)	MAGNESIUM L-THREONATE	1 mg
BETAINE (UNII: 3SCV180C9W) (BETAINE - UNII:3SCV180C9W)	BETAINE	500 ug
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1.83 mg
SODIUM CITRATE (UNII: 1Q73Q2JULR) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CITRATE	3.67 mg

Inactive Ingredients

Ingredient Name	Strength
ANNATTO (UNII: 6PQP1V1B6O)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PIPERINE (UNII: U71XL721QK)	
WATER (UNII: 059QF0KO0R)	
UBIDECARENONE (UNII: EJ27X76M46)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

Product Characteristics

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

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

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

Revised: 10/2022

Jaymac Pharma