

ENLYTE- leucovorin, folic acid, 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, delayed release pellets

Jaymac Pharma

EnLyte® with DeltaFolate™

EnLyte®

with DeltaFolate™

[15 mg DFE]

JAYMAC Pharmaceuticals, LLC

Softgels (30ct bottle)

Medical Food For Therapeutic Use

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 for these patients.

Each **EnLyte®** softgel capsule contains: 50 mcg adenosylcobalamin (vitamin B12) 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 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.

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 B12 (adenosylcobalamin), FAD (flavin adenine dinucleotide), NADH (nicotinamide adenosine dinucleotide hydride), vitamin B6 (pyridoxal 5' phosphate), vitamin B1 (thiamine pyrophosphate).

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

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.

INDICATIONS:

CLINICAL DIETARY MANAGEMENT OF MAJOR DEPRESSIVE DISORDER.

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 B₁₂.

PRECAUTIONS:

Folic acid, including reduced forms such as folinic acid, in daily doses above 0.1 mg 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 and must be administered under the supervision of a licensed medical practitioner.

DOSAGE AND ADMINISTRATION:

The usual dose is one EnLyte® softgel capsule given daily with or without food, or as directed under medical supervision. No age restrictions.

KEEP THIS OUT OF THE REACH OF CHILDREN.

Do not exceed the recommended dose.

HOW SUPPLIED:

Oval, brownish orange softgel capsule with imprint ENL.

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.)

JAYMAC Pharmaceuticals LLC, 2085 I-49 S. Service Rd Sunset, LA 70584

MANUFACTURED AND/OR PACKAGED IN USA/INDIA

Rev Nov 8 2023 (V9)

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.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 30 SOFTGELS Bottle Label

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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.

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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)

64661-711-30*

USE UNDER MEDICAL SUPERVISION



EnLyte
with DeltaFolate[™]
(L-methylfolate Mg/Folic Acid/Folic Acid)



SOFTGELS (30ct BOTTLE)

Medical Food

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ENLYTE

leucovorin, folic acid, 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, cobamide, cocarboxylase (thiamine pyrophosphate), magnesium ascorbate, zinc ascorbate, magnesium L-threonate and betaine capsule, delayed release pellets

Product Information

Product Type	MEDICAL FOOD	Item Code (Source)	NHRC:64661-711
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEUCOVORIN (UNII: Q573I9DVLP) (LEUCOVORIN - UNII:Q573I9DVLP)	LEUCOVORIN	2.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
LEVOMEFOLATE MAGNESIUM (UNII: 1VZZ62R081) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	7 mg
FERROUS CYSTEINE GLYCINATE (UNII: 8B4OP7RK5N) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CYSTEINE GLYCINATE	13.6 mg
1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM (UNII: 6VMM73T46K) (1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-	1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE	6.4 mg

PHOSPHOSERINE - UNII:DVY071LF1W)	CALCIUM	
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	ENL
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:64661-711-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
medical food		08/12/2011	

Labeler - Jaymac Pharma (830767260)

Registrant - Jaymac Pharma (830767260)

Establishment

Name	Address	ID/FEI	Business Operations
Ocean Healthcare Pvt Ltd		873673519	manufacture

Revised: 12/2023

Jaymac Pharma