

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, 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 15 mg DFE of reduced folates from DeltaFolate™ .

*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.

ALSO CONTAINS: 24 mg l-ascorbate magnesium, 20 mg phospholipids, 1.5 mg elemental iron (ferrous glycine cysteinat), 1 mg l-ascorbate zinc, 1 mg l-threonate magnesium, 50 mcg adenosylcobalamin, 25 mcg thiamine pyrophosphate, 25 mcg flavin adenine dinucleotide, 25 mcg nicotinamide adenosine dinucleotide hydride, 25 mcg pyridoxal 5' phosphate.

EXCIPIENTS: annatto, betaine, citrates, gelatin, glycerin, natural orange flavor, olive oil, piperine, purified water, sunflower lecithin, ubidecarenone (CoQ10), yellow beeswax.

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

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. L-methylfolate is not interchangeable with folic acid. Folic acid is not effective in some patients in impacting cerebral folate levels due to low rates of folic acid transport across the blood-brain barrier and/or low brain levels of the enzyme required to convert folic acid into a biological and functional form.

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, Sunset, LA 70584

MANUFACTURED AND/OR PACKAGED IN USA/INDIA

Rev July 28 2022

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 30 SOFTGELS Bottle Label

DESCRIPTION: EnLyte® is a medical food for use **only** under medical supervision to assist MTHFR SNP (VLEs) and methylation 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 15 mg DFE of reduced folates from DeltaFolate™.

A recent study* suggested that EnLyte® was effective in lowering homocysteine levels in 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 C677T or A1298C Polymorphism

INGREDIENTS: 7 mg L-methylfolate magnesium, ~2.5 mg folic acid and ~1 mg DHE.

ALSO CONTAINS: 24 mg L-ascorbate magnesium, 20 mcg phospholipids, 1.5 mg elemental iron (ferrous glycine cysteinate), 1 mg L-ascorbate zinc, 1 mg L-threonate magnesium, 50 mcg adenosylcobalamin, 25 mcg thiamine pyrophosphate, 25 mcg flavin adenine dinucleotide, 25 mcg nicotinamide adenine dinucleotide hydride, 25 mcg pyridoxal 5' phosphate.

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

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

PRECAUTIONS: Folic acid, including reduced forms such as folic 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.

L-methylfolate is not interchangeable with folic acid. Folic acid is not effective in some patients in impacting cerebral folate levels due to low rates of folic acid transport across the blood-brain barrier and/or low brain levels of the enzyme required to convert folic acid into a biological and functional form.

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.

64661-711-30*

USE UNDER MEDICAL SUPERVISION



SOFTGELS (30ct BOTTLE)

Medical Food

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 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.

JAYMAC Pharmaceuticals, LLC, Sunset, LA 70584 / MANUFACTURED AND/OR PACKAGED IN USA/INDIA

July 28 2022 (V5)



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, cobamamide, 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)	NHRIC: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: 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: FOR1QK73KB) (COBAMAMIDE - UNII:FOR1QK73KB)	COBAMAMIDE	50 ug
COCARBOXYLASE (UNII: Q57971654Y) (COCARBOXYLASE - UNII:Q57971654Y)	COCARBOXYLASE	25 ug
MAGNESIUM ASCORBATE (UNII: 0N1G678593) (ASCORBIC ACID -	MAGNESIUM ASCORBATE	25 mg

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
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Ocean Healthcare Pvt Ltd		873673519	manufacture
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Revised: 7/2022

Jaymac Pharma