

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 Pharmaceuticals LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

EnLyte® with DeltaFolate™

EnLyte®

with DeltaFolate™

[2.5 mg F-THf, 1mg PteGlu, 7mg Me-THf][50 mcg CBI][1.5 mg FeGC]

ANTI-ANEMIA PREPARATION

as folate, cobalamin & iron

Certified 3rd-party GLUTEN-FREE

JAYMAC Pharmaceuticals, LLC

Softgels (30ct bottle)

Prescription **Folate/Hematinic Drug** For Therapeutic Use

Description

EnLyte® is an orally administered prescription **folate/hematinic** drug for *therapeutic use* formulated for adult macrocytic anemia patients - ages 12 and up, who are under specific direction and monitoring of folate, cobalamin and iron status by a physician. **EnLyte®**, through passive diffusion of folate-vitamins, is intended to address the increased need for *metabolically-active* forms of folate in the cerebrospinal fluid, plasma, and/or red blood cells in patients with MTHFR (*at alleles C667T, A1298C and/or G1793A*) and/or macrocytic anemia. **EnLyte®** may be useful in patients at risk of depression due to a deficiency of folate and/or cobalamin. **EnLyte®** may be taken by women of childbearing age. **EnLyte®** may be taken by geriatric patients where compliance is an issue.

FUNCTIONAL EXCIPIENTS: 25 mg ascorbates 5,6 (24 mg magnesium l-ascorbate, 1 mg zinc l-ascorbate) [antioxidant], at least 5.5 mg citrates (at least 1.83 mg citric acid, at least 3.67 mg sodium citrates) [stabilizers], at least 23.33 mg phospholipid-omega complex⁷ [marine lipids], 500 mcg betaine (trimethylglycine) [acidifier], 1 mg magnesium l-threonate [stabilizer]

OTHER EXCIPIENTS: "Annatto color" (as a blend of annatto with stomach substance [thickener/stabilizer]) [colorant], flavin adenine dinucleotide 8 (FAD), gelatin (bovine), glycerine, plant lipids (sunflower) [lecithin], nicotinamide adenine dinucleotide hydride 8 (NADH), pyridoxal 5' phosphate⁶ (P5P), piperine [bioavailability enhancer], purified water, thiamine pyrophosphate 8, ubidecarenone [antioxidant], yellow beeswax.

5 30% daily value (DV) of VITAMIN C, and 10% DV IRON for geriatrics

6 NOT a significant source of magnesium and zinc.

7 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)

8 Contains less than 2% (<25 mcg/each) of vitamins B1, B2, B3 and B6.

CONTAINS FISH/KRILL/SOY. Certified 3rd-party GLUTEN-FREE. No artificial colorants. No dairy, wheat, sugar or egg.

INDICATIONS:

EnLyte® is indicated in the treatment of folate-induced macrocytic anemias – including megaloblastic anemias, resulting from deficiency - including megaloblastic anemias, and the prevention of cobalamin deficiency. **EnLyte®** is indicated in the maintenance of normal hematologic status (hematopoiesis) as well as supplement for other folate and cobalamin deficiencies.

WARNINGS:

- 1. USE OF THIS PRODUCT WITHOUT DIRECT SUPERVISION OF A PHYSICIAN IS DANGEROUS.**
- 2. Some patients afflicted with pernicious anemia may or not respond to the orally ingested vitamin B₁₂, and there is no known way to predict which patients may respond and which patients may cease to respond.*
- 3. Periodic examinations and laboratory studies of pernicious anemia patients are essential and recommended.**
4. The parental administration of (cyano)cobalamin – or vitamin B₁₂, is generally recognized as fully effective treatment of pernicious anemia. Parental *alkyl*-cobalamin preparations have not been and are not authorized for use except by or on the prescription of a physician.

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.

ADVERSE REACTIONS:

Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, feeling of swelling of entire body may occur with administration of cobalamin. Allergic sensitization has been reported following both oral and parenteral administration of folate.

PRECAUTIONS:

0.1 mg or more of folic acid daily may obscure pernicious anemia in that the hematological remission may occur while neurological manifestations remain progressive. The safe tolerable limit for folic acid (in preparations) is 1 mg [emphasis added].

DOSAGE AND ADMINISTRATION:

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

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Do not exceed the recommended dose.

HOW SUPPLIED:

Oval, brownish-orange softgel capsule with “ENL” 7 on one side, in bottles of 30 with NDC 64661-711-30.

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

Rev April 2019

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 30 MULTIPHASIC SOFTGELS Bottle Label

NDC 64661-711-30

Rx Only

**EnLyte®
with DeltaFolate™**

(2.5mg F-THF, 1mg PteGlu CR, 7mg Me-THF-Mg [50 mcg CBI][1.5 mg FeGC]

ANTI-ANEMIA PREPARATION

as folate, cobalamin & iron

Certified 3rd-party GLUTEN-FREE

**JAYMAC
Pharmaceuticals, LLC**

SOFTGELS (30ct BOTTLE)

Prescription Folate/Hematinic Drug

For Therapeutic Use

INGREDIENTS (1.5 mg DVE Folate):

- Reduced folic acid, DVE..... 1 mg¹
- Adenosylcobalamin (cyanocobalamin) (vitamin B12)..... 50 mcg²
- FeGC (ferrous glycine cysteinate) (11.5 mg elemental iron)..... 13.6 mg³

ALSO CONTAINS:

- Fermyfolate acid..... 2.5 mg⁴
- 1-methylfolate..... 7 mg⁴

¹ 1 mg DVE Folate

² cyanocobalamin (the primary form of vitamin B12) is stabilized and is adjusted to the presence of stomach substance

³ Pure anhydrous acid, crystalline iron chelate; Anhydrous under anhydrous license

⁴ From 8 mg DVE 1-methylfolate acid magnesium (methyl folate)

⁵ Anhydrous (Purified Phosphoric Acid, Calcium) U.S. Patent # 7,341,208

FUNCTIONAL EQUIVALENTS: 25 mg ascorbate^{1*} (24 mg magnesium-L-ascorbate, 1 mg other L-ascorbate) (antioxidant), at least 5.5 mg citric acid (at least 2.81 mg citric acid) at least 7.67 mg sodium citrate (stabilizer), at least 23.33 mg phosphate-magnesium core plus (crystal hydrate), 500 mg calcium hydroxyapatite (stabilizer), 1 mg magnesium-L-threonate (stabilizer)

OTHER INGREDIENTS: "Menthololol" (as a blend of amounts with stomach substance (fishbone/stabilizer)) (colony), flavin adenosyl cobalamin (FAD), gelatin (bovine), glycerine, plant fiber (cellulose) (filler), microcrystalline cellulose, dicalcium phosphate (FAD), pyridoxal 5' phosphate (P55), piperine (bioavailability enhancer), purified water, thiamine pyrophosphate², white wax (antioxidant), yellow beeswax.

¹ 300 mg daily rate (N) of VITAMIN C and 30% DV (N) for gelatin

² NCI (National Cancer Institute) source of mesoporphyrin and iron

³ Contains at least 12 mg phosphate (P55) - of which approximately 6.4 mg is P5-20A-G, and less than 16.6% (1:800) mg P5-20A-G

⁴ Contains less than 2% (<25 mg/kg) of vitamins B1, B2, B3 and B6

CONTAINS FISH/BIRD/SOY. Certified 3rd-party GLUTEN-FREE. No artificial colors. No dairy, wheat, sugar or egg.

ADVERSE REACTIONS: Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, feeding of swelling of entire body may occur with administration of cobalamin. Allergic sensitization has been reported following both oral and parenteral administration of folate.

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JAYMAC Pharmaceuticals, LLC, Sunset, LA 70584
MANUFACTURED AND/OR PACKAGED IN USA/CANADA Rev April 2019

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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, cobamamide, cocarboxylase (thiamine pyrophosphate), magnesium ascorbate, zinc ascorbate, magnesium l-threonate and betaine capsule, delayed release pellets

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:6466 1-711
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: 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: 1Y26ZZ0OTM) (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:L4YR4M0NH37)	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: 059QF0K00R)	
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	NDC:64661-711-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/12/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/12/2011	

Labeler - Jaymac Pharmaceuticals LLC (830767260)

Registrant - Jaymac Pharmaceuticals LLC (830767260)

Revised: 6/2019

Jaymac Pharmaceuticals LLC