

**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.*

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**EnLyte® with DeltaFolate™**

EnLyte®

with DeltaFolate™

[50 mcg B12] [2.5 mg F-THf, 1mg PteGlu, 7mg Me-THf]

ANTI-PERNICIOUS ANEMIA B<sub>12</sub>-PREPARATION with B12-cofactor levomefolic acid, magnesium salt.

Prescription **Hematinic Drug** For Therapeutic Use

Softgel Capsules (30ct bottle)

NDC 64661-711-30

**R<sub>x</sub> Only [DRUG]**

**GLUTEN-FREE**

**DESCRIPTION**

EnLyte® is an orally administered prescription **hematinic drug** for therapeutic use formulated for adult macrocytic anemia patients ages 12 and up, who are under specific direction and monitoring of vitamin B<sub>12</sub> status by a physician

**Ingredients**

Adenosylcobalamin (coenzyme B <sub>12</sub> )	50 mcg
Formyltetrahydrofolic acid (B <sub>9</sub> -vitamer)	2.5 mg*
Folic acid, DHF - (provitamin B <sub>9</sub> )	1 mg*
Levomefolic acid, magnesium salt (B <sub>12</sub> cofactor)	7 mg†

\* 6 mg DFE folate (vitamin B<sub>9</sub>) of at least 15 mg DFE total folate

† From 9 mg l-methylfolate (molar equivalent)

**FUNCTIONAL EXCIPIENTS:** 13.6 mg FeGC as ferrous glycine cysteinate (1.5 mg elemental iron<sup>1</sup>) [colorant], 25 mg ascorbates<sup>1,2</sup> (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-omega3 complex<sup>3</sup> [marine lipids], 500 mcg betaine (trimethylglycine) [acidifier], 1 mg magnesium l-threonate [stabilizer].

**OTHER EXCIPIENTS:** Annatto [colorant], flavin adenine dinucleotide<sup>4</sup> (FAD), gelatin (bovine), glycerine, plant lipids (sunflower) [lecithin], natural orange flavor [masking], nicotinamide adenine dinucleotide hydride<sup>4</sup> (NADH), pyridoxal 5 phosphate<sup>6</sup> (P5P), piperine [bioavailability enhancer], purified water, thiamine pyrophosphate<sup>4</sup>, ubidecarnone [antioxidant], yellow beeswax.

**CONTAINS FISH/KRILL/SOY.**

Certified 3<sup>rd</sup>-party **GLUTEN-FREE**. No artificial colorants. No dairy, wheat, sugar or egg.

1 30% daily value (DV) of VITAMIN C, and 10% DV IRON.

2 NOT a significant source of magnesium and zinc.

3 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)

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

**MECHANISM OF ACTION:**

Vitamin B<sub>12</sub>[active]; Vitamin B<sub>9</sub> [prevention]

**INDICATIONS:**

EnLyte® is indicated in the treatment of pernicious anemia, and the prevention of vitamin B9 deficiency.

**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 examination and laboratory studies of pernicious anemia patients are essential and recommended.
4. The parenteral administration of (cyano)cobalamin – or vitamin B12, is generally recognized as a fully effective treatment of pernicious anemia. Parenteral alkyl-cobalamin preparations have not been and are not authorized for use except by or on the prescription of a physician.

**ADVERSE REACTIONS:**

Allergic sensitization has been reported following both oral and parenteral administration of vitamin B9.

**DOSAGE AND ADMINISTRATION:**

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

**Do not exceed recommended dose. Call your medical practitioner about side effects. You may report side effects by calling 866-280-5961.**

**HOW SUPPLIED:**

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

**STORAGE:**

Store at 20°-25°C (68°-77°F). Protect from light and moisture as contact with moisture may produce surface discoloration and/or erosion.

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

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

**MANUFACTURED FOR:**

JayMac Pharmaceuticals, LLC; Sunset, LA 70584.

MANUFACTURED AND/OR PACKAGED IN USA/CANADA.

**PATENTS:**

US Patent No 7,935,365; and other patent applications pending.

**TRADEMARKS:**

EnLyte® is a registered mark of JayMac Pharmaceuticals. DeltaFolate™ is a use-trademark of JayMac Pharmaceuticals.

**Rev August 2017**

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

NDC 64661-711-30††R<sub>x</sub>

**EnLyte®  
with DeltaFolate™**

(2.5mg F-THF, 1mg PteGlu CR, 7mg Me-THF-Mg)

**ANTI-PERNICIOUS ANEMIA B12 - PREPARATION**

with B12-cofactor levomefolic acid, magnesium salt

**JAYMAC**  
Pharmaceuticals, LLC

**SOFTGELS (30ct BOTTLE)**

Prescription Hematinic Drug for Therapeutics Use

**INGREDIENTS:** Each oval, brownish-orange softgel with imprint "ENLYTE" contains:

Adenylcobalamin (coenzyme B<sub>12</sub>)..... 50 mcg  
 Formyltetrahydrofolic acid (B<sub>9</sub>-vitamin)..... 2.5 mg<sup>1</sup>  
 Folic acid, DHF (povidone B<sub>9</sub>)..... 1 mg<sup>1</sup>  
 ALSO CONTAINS: Levomefolic acid, magnesium salt (B<sub>9</sub> cofactor)..... 7 mg<sup>2</sup>  
 FUNCTIONAL EQUIVALENTS: 13.6 mg FeC, as ferrous glycine cysteinylate<sup>3</sup> (1.5-mg elemental iron)<sup>4</sup> (colored), at least 23-33 mg phospholipid-omni-33 complex<sup>5</sup>, at least 5.5 mg citrulline (at least 1.63 mg citrulline acid, at least 3.65 mg sodium citrate) [stabilizer], 25 mg ascorbate<sup>6</sup>, \*24 mg magnesium L-ascorbate, 1 mg zinc L-ascorbate<sup>7</sup>, 500 mg betaine (trimethylglycine) [additive], 1 mg magnesium L-threonate [stabilizer].

**OTHER INGREDIENTS:** Annatto (colorant), FADP, gelatin (bovine), glycerine, plant lipids (sunflower) (lecithin), natural orange flavor (masking), NADH, PVP, piperine (bioavailability enhancer), purified water, thiamine pyrophosphate, ubiquinolone (antioxidant), yellow beeswax.

**CONTAINS FISH/KRILL/SOY.** Certified 3rd-Party Gluten-Free. No artificial colors. No dairy, wheat, sugar or egg.


**ADVERSE REACTIONS:** Allergic sensitization has been reported following both oral & parenteral administration of vitamin B<sub>12</sub>.

**PRECAUTIONS:** 0.1 mg or more of vitamin B<sub>12</sub> daily may obscure pernicious anemia in that the hematologic remission may occur while neurological manifestations remain progressive. The safe tolerable upper limit for vitamin B<sub>12</sub> is 1 mg.

<sup>1</sup> 6 mg DFE folate (vitamin B<sub>9</sub>) of at least 15 mg DFE total folate.  
<sup>2</sup> From 9 mg L-methylfolate (molar equivalent).  
<sup>3</sup> 10% daily value (DV) of VITAMIN C, and 10% DV of IRON.  
<sup>4</sup> Not a significant source of magnesium and zinc.  
<sup>5</sup> Contains at least 12 mg PS of which approximately 6.4 mg as PS-DHA-Ga and less than 1% EPA (< 800 mg PS-EPA-Ca).  
<sup>6</sup> Contains less than 2% (< 25 mg/each) of B<sub>1</sub>, B<sub>2</sub>, B<sub>6</sub>, B<sub>12</sub> as colorants.  
<sup>7</sup> Lower case.

Amindole® (Viva Pharmaceuticals, Canada) U.S. Patent # 7,341,708.


NDC 64661-711-30      Rx Only



**EnLyte**  
with DeltaFolate™

[2.5mg F-THE, 1mg PIGlu, 7mg Me-THE]

**ANTI-PERNICIOUS ANEMIA B<sub>12</sub>-PREPARATION**  
with B<sub>12</sub>-cofactor levomefolic acid, magnesium salt



**JAYMAC**  
Pharmaceuticals, LLC

SOFTGELS (30ct BOTTLE)

Prescription Hematinic Drug  
for Therapeutic Use

**DESCRIPTION:** EnLyte<sup>®</sup> is an orally administered prescription hematinic drug for therapeutic use, formulated for adult macrocytic anemia patients - ages 12 and over, who are under specific direction and monitoring of vitamin B<sub>12</sub> status by a physician.

**INDICATION:** EnLyte<sup>®</sup> is indicated in the treatment of pernicious anemia, and the prevention of vitamin B<sub>12</sub> deficiency.


**DOSAGE AND ADMINISTRATION:** The adult dose is one capsule daily preferably on an empty stomach.

**WARNING:** 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 B<sub>12</sub>, 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 parenteral administration of (cyano)cobalamin - or vitamin B<sub>12</sub> is generally recognized as a fully effective treatment of pernicious anemia. Parenteral allyl-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 866-280-5961. **KEEP THIS OUT OF THE REACH OF CHILDREN.**  
 Do not exceed the recommended dose. **STORAGE:** Store at 20°-25° C (68°-77° F) (Tamper Evident: Do not use if seal is broken or missing.)

**CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION.**

JAYMAC Pharmaceuticals, LLC, Sunset, LA 70384  
 MANUFACTURED AND/OR PACKAGED IN USA/CANADA Rev Aug 17, 2017



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## ENLYTE

leucovorin, folic acid, levomefolic acid, magnesium salt, 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:64661-711
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LEUCOVORIN (UNII: Q573I9DVLV) (LEUCOVORIN - UNII:Q573I9DVLV)	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:GW895810WR)	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: ZC44YT8KK) (FLAVIN ADENINE DINUCLEOTIDE - UNII:ZC44YT8KK)	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: 9T1B3513XW) (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:2968PHW8QP)	ANHYDROUS CITRIC ACID	100 mg	

UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1.65 mg
<b>SODIUM CITRATE</b> (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

<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>	ENL
<b>Contains</b>			

### 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	10/01/2011	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/01/2011	

**Labeler** - Jaymac Pharmaceuticals LLC (830767260)

**Registrant** - Jaymac Pharmaceuticals LLC (830767260)

Revised: 9/2017

Jaymac Pharmaceuticals LLC