

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™

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

ANTI-PERNICIOUS ANEMIA B₁₂-PREPARATION with B12-cofactor levomefolic acid, magnesium salt.

Prescription **Hematinic Drug** For Therapeutic Use

Softgel Capsules (30ct bottle)

NDC 64661-711-30

R_x 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 B₁₂ status by a physician

Ingredients

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

* 6 mg DFE folate (vitamin B9) 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 iron¹) [colorant], 25 mg ascorbates^{1,2} (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 complex³ [marine lipids], 500 mcg betaine (trimethylglycine) [acidifier], 1 mg magnesium l-threonate [stabilizer].

OTHER EXCIPIENTS: Annatto [colorant], flavin adenine dinucleotide⁴ (FAD), gelatin (bovine), glycerine, plant lipids (sunflower) [lecithin], natural orange flavor [masking], nicotinamide adenine dinucleotide hydride⁴ (NADH), pyridoxal 5 phosphate⁶ (P5P), piperine [bioavailability enhancer], purified water, thiamine pyrophosphate⁴, ubidecarnone [antioxidant], yellow beeswax.

CONTAINS FISH/KRILL/SOY.

Certified 3rd-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 B₁₂[active]; Vitamin B₉ [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_x

**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 B₁₂)..... 50 mcg
 Formyltetrahydrofolic acid (B₉-vitamin)..... 2.5 mg¹
 Folic acid, DHF (povidone B₉)..... 1 mg¹
 ALSO CONTAINS: Levomefolic acid, magnesium salt (B₉ cofactor)..... 7 mg²
 FUNCTIONAL EQUIVALENTS: 13.6 mg FeCl₂ as ferrous glycine cysteinylate³ (1.5-mg elemental iron)⁴ (colored), at least 23-33 mg phospholipid-omni-33 complex⁵ and at least 5.5 mg citralex (at least 1.63 mg citric acid, at least 3.65 mg sodium citrate) [stabilizer], 25 mg ascorbate⁶ (24 mg magnesium L-ascorbate, 1 mg zinc L-ascorbate), 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 colorants. No dairy, wheat, sugar or egg.


ADVERSE REACTIONS: Allergic sensitization has been reported following both oral & parenteral administration of vitamin B₁₂.

PRECAUTIONS: 0.1 mg or more of vitamin B₁₂ daily may obscure pernicious anemia in that the hematologic remission may occur while neurological manifestations remain progressive. The safe tolerable upper limit for vitamin B₁₂ is 1 mg.

¹ 6 mg DFE folate (vitamin B₉) of at least 15 mg DFE total folate.
² From 9 mg L-methylfolate (molar equivalent).
³ 10% daily value (DV) of VITAMIN C and 10% DV of IRON.
⁴ Not a significant source of magnesium and zinc.
⁵ 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).
⁶ Contains less than 2% (< 25 mg/each) of B₁, B₂, B₆ & B₁₂ as colorants.


⁷ Lower case.
 Animol® (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-FHE)

ANTI-PERNICIOUS ANEMIA B₁₂-PREPARATION
with B₁₂-cofactor levomefolic acid, magnesium salt



SOFTGELS (30ct BOTTLE)

Prescription Hematinic Drug
for Therapeutic Use

DESCRIPTION: EnLyte™ 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 B₁₂ status by a physician.

INDICATION: EnLyte™ is indicated in the treatment of pernicious anemia, and the prevention of vitamin B₁₂ deficiency.


DOSEAGE 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 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 parenteral administration of (cyano)cobalamin - or vitamin B₁₂ 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: 9T135313XW) (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
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	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