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 mg CBl] *[2.5 mg F-THf, 1mg PteGlu, 7mg Me-THf]*

JAYMAC *Pharmaceuticals, LLC*

Softgels (30ct bottle)

Prescription **Vitamin** *For Therapeutic Use*

Description

EnLyte® is an orally administered prescription **vitamin** for *therapeutic use* formulated for adult patients - ages 12 and up, who are under specific direction and monitoring of homocysteine (HCY) status by a physician. *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.

OTHER INGREDIENTS: Annatto [colorant], 500 mcg betaine (trimethylglycine), at least 5.5 mg citrates (at least 1.83 mg citric acid, at least 3.67 mg sodium citrates), 25 mcg flavin adenine dinucleotide (reduced vitamin B_2), gelatin (bovine), glycerine, 1 mg magnesium l-threonate, 25 mcg nicotinamide adenine dinucleotide hydride (reduced vitamin B_3), piperine, plant lipids (sunflower), purified water, 25 mcg pyridoxal 5’ phosphate (reduced vitamin B_6), 25 mcg thiamine pyrophosphate (reduced vitamin B_1), ubidecarenone, yellow beeswax.

[1]Coenzyme B_{12} is the primary form most found in mammalian liver. [2]Vitamer of B_{12} cofactor, l-methylfolate. [3]Pure amino acid, cysteinated iron chelate. [4] 30% daily value (DV) of VITAMIN C, and 10% DV IRON for geriatrics. [5] 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).

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

INDICATIONS:

EnLyte® is indicated in the TREATMENT of vitamin deficiency - specifically vitamin B_{12} deficiency, and the PREVENTION of vitamin B_{12}-cofactor deficiency, l-methylfolate. *Also contains a small amount of SUPPLEMENTATION in the form of iron and other folates along with vitamin C and phospholipids.*

MECHANISM OF ACTION:

VITAMIN B_{12} [**TREATMENT**]; FOLATE [*PREVENTION*]; OTHER [*SUPPLEMENTATION*];

WARNINGS:

1. **Caution: This product is not suitable for the TREATMENT of vitamin B_{12} deficiency secondary to either pernicious anemia and/or gastrointestinal malabsorption (i.e., exocrine pancreatic insufficiency).**
2. *Caution: The use of vitamin B_{12} for the TREATMENT of anemnia without direct supervision of a physician may be dangerous.*

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 vitamin B_{12}. Allergic sensitization has been reported following both oral and parenteral administration of vitamin B_9.

PRECAUTIONS:

0.1 mg or more of vitamin B_9 daily may obscure pernicious anemia in that the hematological remission may occur while neurological manifestations remain progressive. Exclusive use of vitamin B_9 in treating vitamin B_{12}-deficient macrocytic anemia could result in progressive and irreversible neurological damage. Specifically, vitamin B_{12} deficiency allowed to progress over 3 months may produce permanent degenerative lesions of the spinal cord - as observed when vitamin B_9 therapy is used as the only hematopoietic agent. Doses of vitamin $_{B12}$ exceeding 10 mcg daily may produce hematologic response in patients with vitamin B_9 deficiency. Indiscriminate administration may mask the true diagnosis. *A dietary deficiency of only vitamin B_{12} is rare; multiple vitamin deficiency is expected in any dietary deficiency. No single regimen*

fits all cases, and the status of the patient observed in follow-up is the final criterion for adequacy of therapy.

DOSAGE AND ADMINISTRATION:

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

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.

Do not exceed the recommended dose.

HOW SUPPLIED:

Oval, brownish-orange softgel capsule with imprint **ENL**.

STORAGE:

STORAGE: Store at 20°-25° C (68°-77° F)

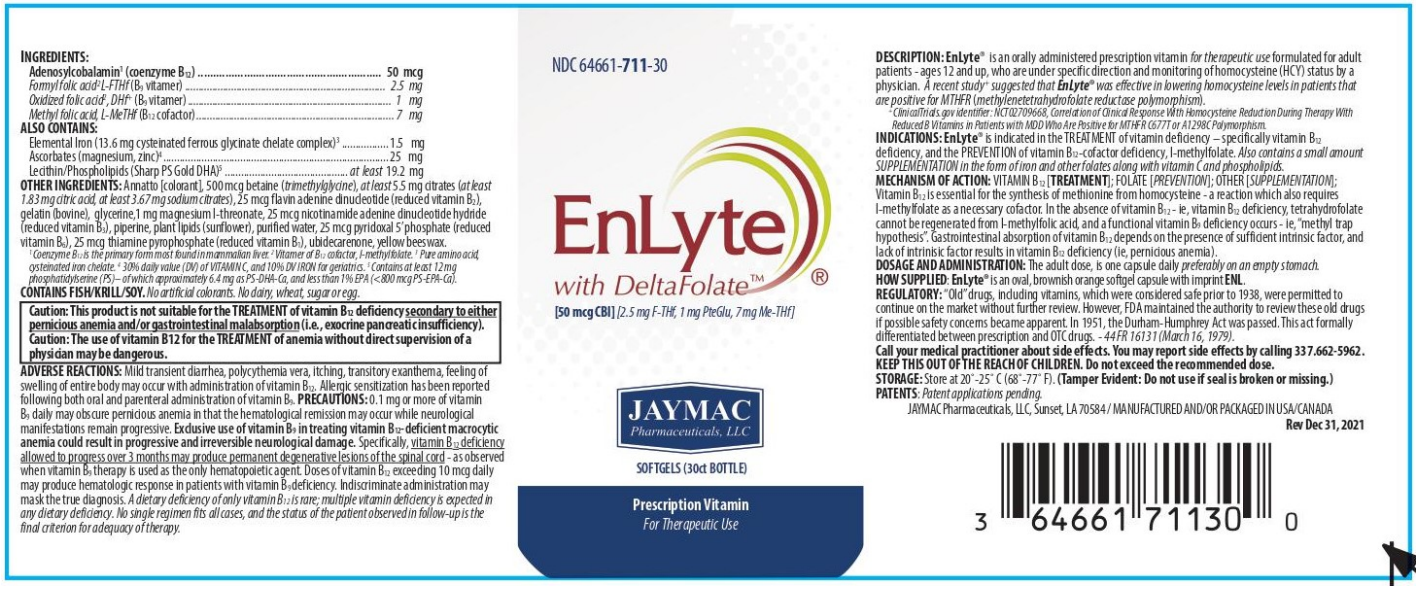
(Tamper Evident: Do not use if seal is broken or missing.)

JAYMAC Pharmaceuticals, LLC, Sunset, LA 70584

MANUFACTURED AND/OR PACKAGED IN USA/CANADA

Rev Dec 27 2021

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 30 SOFTGELS Bottle Label



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: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: 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: ZC44YTI8KK) (FLAVIN ADENINE DINUCLEOTIDE - UNII:ZC44YTI8KK)	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: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	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)

Establishment

Name	Address	ID/FEI	Business Operations
Viva Pharmaceuticals INC		253288898	manufacture(64661-711)

Revised: 12/2021 Jaymac Pharmaceuticals LLC