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™

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

ANTI-ANEMIA PREPARATION *as extrinsic/intrinsic factor concentrate plus folate.*

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 – including pernicious anemia and folate deficiency, ages 12 and up, who are under specific direction and monitoring of cobalamin and folate status by a physician. ***EnLyte®*** *may be useful in patients at risk of depression due to a deficiency of cobalamin and/or folate.* ***EnLyte®*** *may be taken by women of childbearing age.* ***EnLyte®*** *may be taken by geriatric patients where compliance is an issue.*

Ingredients

Cobalamin intrinsic factor complex	1 NF Units*
ALSO CONTAINS (15 mg DFE folate):	
Formylfolic acid	2.5 mg†
Reduced folic acid, DHF	1 mg[1]
L-methylfolic acid	7 mg‡

* *National Formulary Units ("NF UNITS") equivalent to 50 mcg of active coenzyme cobalamin (as adenosylcobalamin concentrate with intrinsic factor)*

† *6 mg DFE folate*

‡ *From 9 mg DFE l-methylfolic acid magnesium (molar equivalent)*

FUNCTIONAL EXCIPIENTS: 13.6 mg FeGC as ferrous glycine cysteinate (*1.5 mg elemental iron*[3]) [colorant], 25 mg ascorbates[3,4] (*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[5] [marine lipids], 500 mcg betaine (*trimethylglycine*) [acidifier], 1 mg magnesium l-threonate [stabilizer].

OTHER EXCIPIENTS: Annatto [colorant], flavin adenine dinucleotide[6] (FAD), gelatin (bovine), glycerine, plant lipids (sunflower) [lecithin], nicotinamide adenine dinucleotide hydride[6] (NADH), pyridoxal 5' phosphate[6] (P5P), piperine [bioavailability enhancer], purified water, thiamine pyrophosphate[6], ubidecarenone [antioxidant], yellow beeswax.

[3] 30% daily value (DV) of VITAMIN C, and 10% DV IRON.

[4] NOT a significant source of magnesium and zinc.

[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)

[6] Contains less than 2% (<25 mcg/each) of vitamins B_1, B_2, B_3 and B_6.

CONTAINS FISH/KRILL/SOY.

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

MECHANISM OF ACTION:

Cobalamin [*treatment*]; **Folate**[*prevention*]; **Intrinsic Factor**[*facilitator*].

[*Cobalamin*]

Cobalamin deficiency results in megaloblastic anemia, GI lesions, and neurological damage that begins with an inability to produce myelin and is followed by gradual degeneration of the axon and nerve head. *cobalamin has hematopoietic activity apparently identical to that of the anti-anemia factor in purified liver extract.*

[*Cobalamin*] / [*Intrinsic factor*]

Gastrointestinal absorption of cobalamin depends on the presence of sufficient intrinsic factor. Intrinsic factor deficiency causes pernicious anemia - which may be associated with subacute combined degeneration of the spinal cord.

[*Folate*]

Folate deficiency results in megaloblastic anemia. Folate stimulates specifically the production of red blood cells, white blood cells, and platelets in persons suffering from certain megaloblastic anemias.

Folic acid, formylfolic acid and l-methylfolic acid metabolism results in the creation of tetrahydrofolic acid by different pathways. Both formylfolic acid and l-methylfolic acid acid do not require dihydrofolate reductase (DHR), however folic acid does.

[*Folate*] / [*Cobalamin*]

Cobalamin is essential for the synthesis of methionine from homocysteine - a reaction which also requires folate. In the absence of cobalamin, tetrahydrofolate cannot be regenerated from 5-methyltetrahydrofolate, and a functional folate deficiency occurs (ie, “methyl trap hypothesis”).

Inborn errors of metabolism (IEMs) - such as methyltetrahydrofolate reductase (MTHFR), may also inhibited cobalamin intracellular conversion due to impaired ability to metabolize folic acid.

INDICATIONS:

EnLyte® is indicated in the treatment of macrocytic anemias resulting from cobalamin deficiency - including pernicious anemia, and the prevention of folate deficiency.

EnLyte® is indicated as a primary and adjunctive treatment in megaloblastic anemia associated with tropical and non-tropical sprue, in anemias of nutritional origen, pregnancy, alcoholism, infancy and childhood as well as pernicious anemia patients having idiosyncrasy or sensitivity to parenteral administration (or when parental therapy is refused).

EnLyte® is indicated in the maintenance of normal hematologic status (hematopoiesis) as well as supplement for other cobalamin deficiencies, including:

1. Dietary deficiency of cobalamin occurring in strict vegetarians.
2. Malabsorption of cobalamin resulting from structural or functional damage to the stomach - where intrinsic factor is secreted, or to the ileum, where intrinsic factor facilitates cobalamin absorption. These conditions include HIV infections, AIDS, Crohn’s disease, tropical sprue, and nontropical sprue (idiopathic steatorrhea, gluten-induced enteropathy). Folate deficiency in these patients is usually more severe than cobalamin deficiency.
3. Inadequate secretion of intrinsic factor, resulting from lesions that destroy the gastric mucosa (ingestion of corrosives, extensive neoplasia), and a number of conditions associated with a variable degree of gastric atrophy (such as multiple sclerosis, HIV infection, AIDS, certain endocrine disorders, iron deficiency, and subtotal gastrectomy). Total gastrectomy always produces cobalamin deficiency. Structural lesions leading to cobalamin deficiency include regional ileitis, ileal resections, malignancies, etc.
4. Competition for cobalamin by intestinal parasites or bacteria. The fish tapeworm (Diphyllobothrium latum - usually found in raw fish such as sushi) absorbs huge quantities of cobalamin and infested patients often have associated gastric atrophy. The blind loop syndrome may produce deficiency of cobalamin or folate.
5. Inadequate utilization of cobalamin. This may occur if antimetabolites fo the vitamin are employed in the treatment of neoplasia.

Requirements of cobalamin and/or folate in excess of normal (due to pregnancy, thyrotoxicosis, hemolytic anemia, hemorrhage, malignancy, hepatic and renal disease) can usually be met with oral supplementation.

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 cobalamin, 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 cobalamin, 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.

PRECAUTIONS:

GENERAL:

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].

Folic acid is not a substitute for vitamin B_{12} - although it may improve vitamin B_{12}-deficient megaloblastic anemia. Exclusive use of folic acid in treating vitamin B_{12}-deficient megaloblastic anemia could result in progressive and irreversible neurologic damage. Specifically, vitamin B_{12} deficiency allowed to progress over 3 months may produce permanent degenerative lesions of the spinal cord - as observed when folate therapy is used as the only hematopoietic agent.

Doses of vitamin B_{12} exceeding 10 mcg daily may produce hematologic response in patients with folate 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.

DRUG INTERACTIONS:

Colchicine, para-aminosalicylic acid, and heavy alcohol intake for longer than 2 weeks may produce malabsorption of cobalamin.

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.

DOSAGE AND ADMINISTRATION:

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

As a general rule - in patients with Addisonian Pernicious Anemia, treatment will be required for the remainder of the patient's life. Reticulocyte plasma count, cobalamin and folate must be obtained prior to treatment.

Do not exceed recommended dose. **Call your medical practitioner about side effects. You may report side effects by calling 337.662-5962.**

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.*

Rx Only [DRUG]

Caution: **Federal law prohibits dispensing without a prescription.**

KEEP OUT OF THE REACH OF CHILDREN.

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

[7] *Lower case.*

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.

Revision 3(*November 14, 2018*

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

NDC 64661-**711**-30

℞ Only

[1 NF Units]

EnLyte

with DeltaFolate™®

[2.5mgF-THf, 1mg PteGlu, 7mgMe-THf]

ANTI-ANEMIA PREPARATION

as extrinsic/intrinsic factor complex plus folate

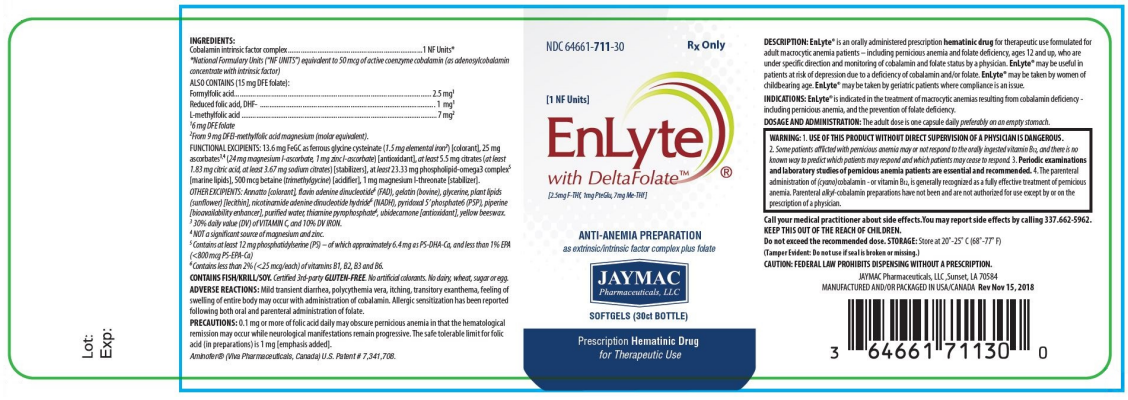
JAYMAC

Pharmaceuticals, LLC

SOFTGELS (30ct BOTTLE)

Presciption Hematinic Drug

For Therapeutic Use



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: Q579716 54Y) (COCARBOXYLASE - UNII:Q579716 54Y)	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	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: 12/2018 Jaymac Pharmaceuticals LLC