EnLyte®
with DeltaFolate™
*[**2.5 mg F-THf, 1mg PteGlu, 7mg Me-THf**] [50 mcg CBI] [1.5 FeGC]*
ANTI-ANEMIA PREPARATION *as folate, cobalamin & iron.*
Prescription **Folate/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 **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®*** *may be useful in patients at risk of depression due to a deficiency of folate and/or cobalamin.*

EnLyte® *is intended to address the increased need for metabolically-active variants of folate vitamers in the cerebrospinal fluid, plasma, and/or red blood cells - as may be found in the SNP (Single-Nucleotide Polymorphisms) known as MTHFR (MethyleneTetraHydroFolate Reductase).* ***EnLyte®*** *achieves this through passive diffusion of these different biologically-active vitamers.*

EnLyte® *may be taken by women of childbearing age.* ***EnLyte®*** *may be taken by geriatric patients where compliance is an issue.*

INGREDIENTS *(15 mg DFE folate)*:

Formylfolic acid	2.5 mg[1]
Reduced folic acid, DHF-	1 mg[1]
L-methylfolic acid	7 mg[2]

[1] *6 mg DFE folate*
[2] *From 9 mg DFE l-methylfolic acid magnesium (molar equivalent).*

ALSO CONTAINS:

Adenosylcobalamin (coenzyme B_{12})	50 mcg[3]
FeGC (cysteinated-ferrous amino-acid chelate)	13.6 mg[4]

[3] *coenzyme B_{12}, is the primary form most found in mammalian liver, and is stabilized and pH-adjusted in the presence of stomach substance*
[4] *1.5 mg elemental iron*

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 3 complex [7] [marine lipids], 500 mcg betaine (*trimethylglycine*) [acidifier], 1 mg magnesium l-threonate [stabilizer]

OTHER EXCIPIENTS: "Annatto color" (as a blend of annatto, E101, stomach substance-CBI complex for soft gelatin capsule shell [stabilizer]) [colorant], flavin adenine dinucleotide [7] (FAD), gelatin (bovine), glycerine, plant lipids (sunflower) [lecithin], nicotinamide adenine dinucleotide hydride [7] (NADH), pyridoxal 5' phosphate [7] (P5P), piperine [bioavailability enhancer], purified water, thiamine pyrophosphate [7], ubidecarenone [antioxidant], yellow beeswax.

[5] *20% daily value (DV) of VITAMIN C, and 5% 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.*

MECHANISM OF ACTION:
Folate [*treatment*]; **Cobalamin** [*prevention*]; and ***Iron*** [*prophylactic*].
[*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 do not require dihydrofolate reductase (DHR), however folic acid does.
[*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.*
[*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 inhibit cobalamin intracellular conversion due to impaired ability to metabolize folic acid.

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.
Requirements of folate and/or cobalamin 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 reticulocyte plasma count, folate and cobalamin status 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**" [9] 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***.
[9] *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 (*April 2019*)

EnLyte® with DeltaFolate™