

**PAXLYTE- 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 capsule  
Jaymac Pharmaceuticals**

*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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## **PaxLyte**

### **PRECAUTIONS**

Folic Acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B<sub>12</sub> is deficient. Daily doses of 0.1 mg or more of folic acid (vitamin B<sub>9</sub>) may obscure pernicious anemia. Hematologic improvement can occur while neurological damage progresses. Exclusive use of folic acid to treat vitamin B<sub>12</sub>-deficient macrocytic anemia can lead to progressive and irreversible neurological damage. Vitamin B<sub>12</sub> deficiency allowed to progress for over 3 months may cause permanent spinal cord lesions. Doses of vitamin B<sub>12</sub> exceeding 10 mcg daily may produce hematologic response in patients with vitamin B<sub>9</sub> deficiency. Indiscriminate administration may mask the true diagnosis.

### **ADVERSE REACTIONS**

Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, feeling of swelling of entire body may occur with administration of vitamin B<sub>12</sub>. Allergic sensitization has been reported following both oral and parenteral administration of vitamin B<sub>9</sub>.

### **DESCRIPTION**

PaxLyte is an orally administered prescription vitamin for therapeutic use formulated for patients who are under specific direction and monitoring of homocysteine (HCY) status by a physician. It is specifically formulated for patients with deficiencies in folate and vitamin B<sub>12</sub>, including those with genetic polymorphisms affecting homocysteine metabolism. A recent study<sup>+</sup> suggested that PaxLyte was effective in lowering homocysteine levels in patients that are positive for MTHFR (methylenetetrahydrofolate reductase polymorphism).

<sup>+</sup> 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.

## INDICATION

PaxLyte is indicated in the TREATMENT of vitamin deficiency – specifically vitamin B<sub>12</sub> deficiency, and the PREVENTION of vitamin B<sub>12</sub>-cofactor deficiency, l-methylfolate.

## MECHANISM OF ACTION

VITAMIN B<sub>12</sub> [TREATMENT]; FOLATE [PREVENTION]; OTHER [SUPPLEMENTATION]; Vitamin B<sub>12</sub> is essential for the synthesis of methionine from homocysteine - a reaction which also requires l-methylfolate as a necessary cofactor.

## DOSAGE AND ADMINISTRATION

The normal dose, is one capsule daily OR as directed by a licensed healthcare practitioner; *preferably on an empty stomach.*

## HOW SUPPLIED

PaxLyte is an oval, brownish orange softgel capsule with imprint 7N3 (NDC 64661-217-30\*).

\* This product is a prescription-folate with or without other dietary ingredients that – due to increased folate levels (AUG 2 1973 FR 20750), requires an Rx on the label because of increased risk associated with masking of B12 deficiency (pernicious anemia). Due to the risk of obscuring pernicious anemia, this product requires licensed medical supervision, an Rx status, and a National Drug Code (NDC) or similarly-formatted product code, as required by pedigree reporting requirements and supply-chain control as well as in some cases, for insurance-reimbursement applications.

## CONTAINS

### Each PaxLyte Softgel Contains:

Adenosylcobalamin <sup>1</sup> (vitamin B <sub>12</sub> ) .....	50 mcg
Folinic Acid (B <sub>9</sub> vitamer).....	2.5 mg
Folic Acid (B <sub>9</sub> vitamer).....	1 mg
L-Methylfolate Magnesium (B <sub>9</sub> vitamer).....	7 mg

**OTHER INGREDIENTS:** Olive oil, gelatin, glycerin, magnesium ascorbate, at least 20 mg Phosphatidylserine DHA Complex (Sharp-PS® Gold)<sup>2</sup>, yellow beeswax, sodium citrate, sunflower lecithin, citric acid, annatto extract, 1.5 mg elemental iron (as ferrous glycine cysteinate)<sup>3</sup>, zinc ascorbate, 1 mg magnesium l-threonate, natural orange flavor, piperine, CoQ10 (ubidecarenone), betaine, 25 mcg flavin adenine dinucleotide (reduced vitamin B<sub>3</sub>), 25 mcg nicotinamide adenosine dinucleotide hydride (reduced vitamin B<sub>2</sub>), 25 mcg pyridoxal 5' phosphate (reduced vitamin B<sub>6</sub>), 25 mcg thiamine pyrophosphate (reduced vitamin B<sub>1</sub>).

<sup>1</sup> Adenosylcobalamin is an active coenzyme form of Vitamin B<sub>12</sub> found in the human body.

<sup>2</sup> 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).

<sup>3</sup> Pure amino acid, cysteinated iron chelate. CONTAINS FISH/KRILL/SOY. No artificial colorants. No dairy, wheat, sugar or egg.

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

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Folic Acid (B-vitamin)	2.5 mg
Folic Acid (B-vitamin)	1 mg
L-Methylfolate Magnesium (B-vitamin)	7 mg

**OTHER INGREDIENTS:** Olive oil, gelatin, glycerin, magnesium ascorbate, at least 20 mg Phosphatidylserine DHA Complex (Sharp-PS® Gold)<sup>2</sup>, yellow beeswax, sodium citrate, sunflower lecithin, citric acid, annatto extract, 1.5 mg elemental iron (as ferrous glycine cysteinylate), zinc ascorbate, 1 mg magnesium l-threonate, natural orange flavor, piperine, CoQ10 (ubiquinone), betaine, 25 mcg flavin adenine dinucleotide (reduced vitamin B<sub>2</sub>), 25 mcg nicotinamide adenine dinucleotide hydride (reduced vitamin B<sub>3</sub>), 25 mcg pyridoxal 5' phosphate (reduced vitamin B<sub>6</sub>), 25 mcg thiamine pyrophosphate (reduced vitamin B<sub>1</sub>).

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NDC 64661-217-30

SOFTGELS (30ct BOTTLE)

Prescription Vitamin

**Rx Only**

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**MECHANISM OF ACTION: VITAMIN B<sub>12</sub> (TREATMENT); FOLATE (PREVENTION); OTHER (SUPPLEMENTATION):** Vitamin B<sub>12</sub> is essential for the synthesis of methionine from homocysteine – a reaction which also requires l-methylfolate as a necessary cofactor.

**DOSAGE AND ADMINISTRATION:** The normal dose, is one capsule daily OR as directed by a licensed healthcare practitioner; preferably on an empty stomach.

**HOW SUPPLIED:** PaxLyte is an oval, brownish orange softgel capsule with imprint 7N3 (NDC 64661-217-30<sup>1</sup>).

<sup>1</sup>This product is a prescription-folate with or without other dietary ingredients that – due to increased folate levels (AUG 2 1973 FR 20750), requires an Rx on the label because of increased risk associated with masking of B<sub>12</sub> deficiency (pernicious anemia). Due to the risk of obscuring pernicious anemia, this product requires licensed medical supervision, an Rx status, and a National Drug Code (NDC) or similarly-formatted product code, as required by pedigree reporting requirements and supply-chain control as well as in some cases, for insurance-reimbursement applications.

**Call your medical practitioner about side effects. You may report side effects by calling (337) 351-6721**


**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.)

**PATENTS:** Patent applications pending.

JAYMAC Pharmaceuticals, LLC, Sunset, LA 70584 / MANUFACTURED AND/OR PACKAGED IN USA/INDIA

V7 (July 24 2024)



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## PAXLYTE

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 capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:64661-217
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LEUCOVORIN</b> (UNII: Q573I9DVLP) (LEUCOVORIN - UNII:Q573I9DVLP)	LEUCOVORIN	2.5 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>LEVOMEFOLATE MAGNESIUM</b> (UNII: 1VZZ 62R081) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	7 mg
<b>FERROUS CYSTEINE GLYCINATE</b> (UNII: 8B4OP7RK5N) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CYSTEINE GLYCINATE	13.6 mg
<b>1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM</b> (UNII: 6WJM73T46K) (1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE - UNII:DVY07ILF1W)	1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM	6.4 mg
<b>1,2-ICOSAPENTOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM</b> (UNII: 9ABD9DRK7B) (1,2-ICOSAPENTOYL-SN-GLYCERO-3-PHOSPHOSERINE - UNII:C3019D8IIA)	1,2-ICOSAPENTOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM	800 ug
<b>PHOSPHATIDYL SERINE</b> (UNII: 394XK0IH40) (PHOSPHATIDYL SERINE - UNII:394XK0IH40)	PHOSPHATIDYL SERINE	12 mg

<b>PYRIDOXAL PHOSPHATE ANHYDROUS</b> (UNII: F06SGE49M6) (PYRIDOXAL PHOSPHATE ANHYDROUS - UNII:F06SGE49M6)	PYRIDOXAL PHOSPHATE ANHYDROUS	25 ug
<b>FLAVIN ADENINE DINUCLEOTIDE</b> (UNII: ZC44YT18KK) (FLAVIN ADENINE DINUCLEOTIDE - UNII:ZC44YT18KK)	FLAVIN ADENINE DINUCLEOTIDE	025 ug
<b>NADH</b> (UNII: 4J24DQ0916) (NADH - UNII:4J24DQ0916)	NADH	25 ug
<b>COBAMAMIDE</b> (UNII: F0R1QK73KB) (COBAMAMIDE - UNII:F0R1QK73KB)	COBAMAMIDE	50 ug
<b>COCARBOXYLASE</b> (UNII: Q57971654Y) (COCARBOXYLASE - UNII:Q57971654Y)	COCARBOXYLASE	25 ug
<b>MAGNESIUM ASCORBATE</b> (UNII: 0N1G678593) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	24 mg
<b>ZINC ASCORBATE</b> (UNII: 9TI35313XW) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ZINC ASCORBATE	1 mg
<b>MAGNESIUM L-THREONATE</b> (UNII: 1Y26ZZ00TM) (THREONIC ACID, L- - UNII:75B0PMW2JF)	MAGNESIUM L-THREONATE	1 mg
<b>BETAINE</b> (UNII: 3SCV180C9W) (BETAINE - UNII:3SCV180C9W)	BETAINE	500 mg
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1.83 mg
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CITRATE	1.83 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ANNATTO</b> (UNII: 6PQP1V1B6O)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>PIPERINE</b> (UNII: U71XL721QK)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>UBIDECARENONE</b> (UNII: EJ27X76M46)	
<b>YELLOW WAX</b> (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>		<b>Imprint Code</b>	7N3
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64661-217-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

unapproved drug other		08/01/2024	
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**Labeler** - Jaymac Pharmaceuticals (830767260)

**Registrant** - Jaymac Pharmaceuticals (830767260)

**Establishment**

Name	Address	ID/FEI	Business Operations
Ocean Healthcare Pvt Ltd		873673519	manufacture(64661-217)

Revised: 8/2024

Jaymac Pharmaceuticals