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.

PaxLyte

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_{12}, including those with genetic polymorphisms affecting homocysteine metabolism. A recent study[+] suggested that PaxLyte was effective in lowering homocysteine 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.

CONTAINS

Each PaxLyte Softgel Contains:

Adenosylcobalamin[1] (vitamin B_{12}) ..... 50 mcg

Folinic Acid (B_9 vitamer)..... 4.25 mg DFE (2.5 mg)

Folic Acid (B_9 vitamer)..... 1.7 mg DFE (1 mg)

L-Methylfolate Magnesium (B_9 vitamer)..... 11.9 mg DFE (7 mg)

OTHER INGREDIENTS: Olive oil, gelatin, glycerin, magnesium ascorbate, at least 20 mg Phosphatidylserine DHA Complex (Sharp-PS® Gold)[2], yellow beeswax, sodium citrate, sunflower lecithin, citric acid, annatto extract, 1.5 mg elemental iron (as ferrous glycine cysteinate)[3], zinc ascorbate, 1 mg magnesium l-threonate, natural orange flavor, piperine, CoQ10 (ubidecarenone), betaine, 25 mcg flavin adenine dinucleotide (reduced vitamin B_3), 25 mcg nicotinamide adenosine dinucleotide hydride (reduced vitamin B_2), 25 mcg pyridoxal 5’ phosphate (reduced vitamin B_6), 25 mcg thiamine pyrophosphate (reduced vitamin B_1).

[1] Adenosylcobalamin is an active coenzyme form of Vitamin B_{12} found in the human body.

[2] 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).

[3] 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.

INDICATION

PaxLyte is indicated in the TREATMENT of vitamin deficiency – specifically vitamin B_{12} deficiency, and the PREVENTION of vitamin B_{12}-cofactor deficiency, l-methylfolate.

MECHANISM OF ACTION

VITAMIN B_{12} [TREATMENT]; FOLATE [PREVENTION]; OTHER [SUPPLEMENTATION]; Vitamin B_{12} 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 practioner; *preferably on an empty stomach.*

HOW SUPPLIED

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

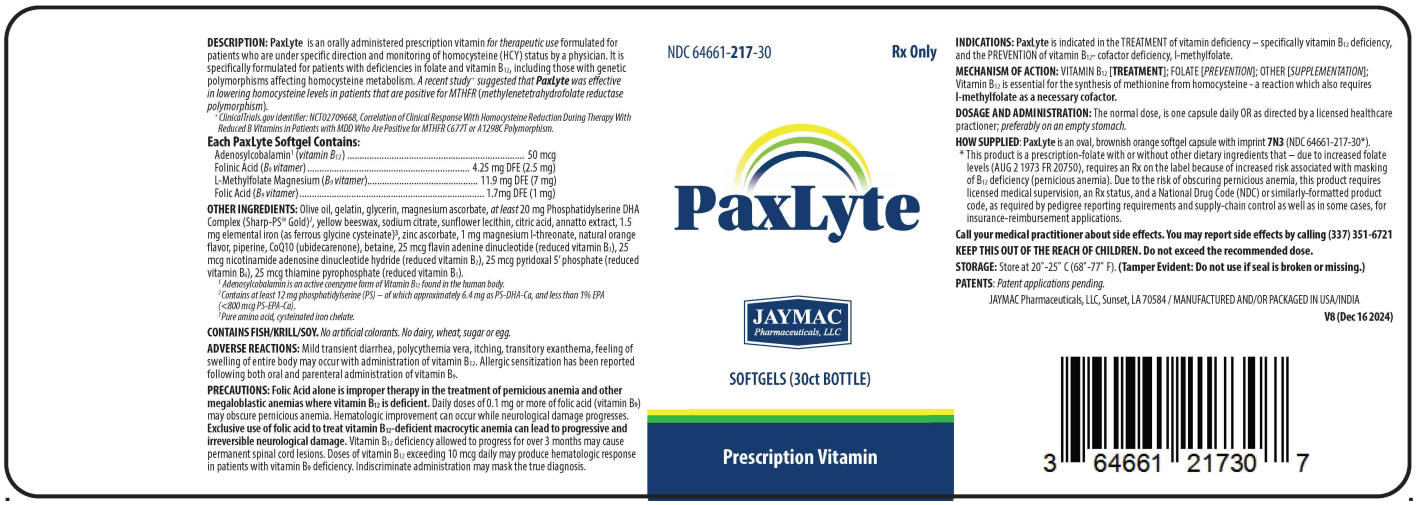
* This product is a prescription-folate with or without other dietary ingredients that – due to increased folate levels (AUG 2 1973 FR 20750), requires an Rx on the label because of increased risk associated with masking of B12 deficiency (pernicious anemia). Due to the risk of obscuring pernicious anemia, 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.

PRECAUTIONS

Folic Acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} is deficient. Daily doses of 0.1 mg or more of folic acid (vitamin B_9) may obscure pernicious anemia. Hematologic improvement can occur while neurological damage progresses. Exclusive use of folic acid to treat vitamin B_{12}-deficient macrocytic anemia can lead to progressive and irreversible neurological damage. Vitamin B_{12} deficiency allowed to progress for over 3 months may cause permanent spinal cord lesions. Doses of vitamin B_{12} exceeding 10 mcg daily may produce hematologic response in patients with vitamin B_9 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_{12}. Allergic sensitization has been reported following both oral and parenteral administration of vitamin B_9.



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

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64661-217
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	025 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)	ASCORBIC ACID	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 mg
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	1.83 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		**Imprint Code**	7N3
Contains			

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			

unapproved drug other		08/01/2024	

Labeler - Jaymac Pharmaceuticals (830767260)

Registrant - Jaymac Pharmaceuticals (830767260)

Establishment

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

Revised: 12/2025 Jaymac Pharmaceuticals