

ENBRACE HR- levomefolate magnesium, leucovorin, folic acid, ferrous cysteine glycinate, magnesium ascorbate, zinc ascorbate, cocarboxylase, flavin adenine dinucleotide, nadh, pyridoxal phosphate anhydrous, cobamamide, betaine, magnesium l-threonate, 1,2-docosahexanoyl-sn-glycero-3-phosphoserine calcium, 1,2-icosapentoyl-sn-glycero-3-phosphoserine calcium, and phosphatidyl serine capsule, delayed release pellets

Jaymac Pharma

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](#).

EnBrace HR™

EnBrace® HR

with DeltaFolate™

[15 mg DFE Folate][50 mcg CBI] [1.5 mg Cys-Fe]

ANTI-ANEMIA PREPARATION

Low-IRON

Prescription **Prenatal Vitamin** *For Therapeutic Use*

SOFTGEL (30ct bottle)

NDC 64661-**650**-30

Rx Only

GLUTEN-FREE

DESCRIPTION:

EnBrace® HR is an orally administered prescription prenatal vitamin *for therapeutic use* formulated for adult patients who are under specific and directr monitoring of a licensed medical practitioner.

EnBrace® HR contains a small amount of iron and may be taken concurrently with iron supplementation.

INGREDIENTS:

Control-release, citrated folic acid, DHF+ (B ₉ - Provitamin)	1 mg ¹
Vitamin B ₁₂ [cobamamide]	50 mcg ²
FeGC [ferrous glycine cysteinate] (1.5 mg elemental iron)	13.6 mg ³
ALSO CONTAINS:	
Folinic acid (B ₉ -vitamer)	2.5 mg ¹
Levomefolic acid (B ₉ & B ₁₂ - cofactor)	5.23 mg ⁴

¹ 6 mg DFE folate (vitamin B₉)

² The form most found in mammalian liver - adjusted for stability and pH in the presence of stomach substance, is a cobamamide, or vitamin B₁₂

³ Pure amino acid, cysteinated iron chelate as AminoFer™* under exclusive license

⁴ 9 mg DFE l-methylfolate magnesium (molar equivalent)

* AminoFer™ (Viva Pharmaceuticals, Canada) U.S. Patent # 7,341,708

FUNCTIONAL EXCIPIENTS: 25 mg ascorbates^{5,6} (24 mg magnesium l-ascorbate, 1 mg zinc l-ascorbate) [antioxidant], at least 23.33 mg phospholipid-omega 3 complex⁷ [marine lipids] , 500 mcg betaine (trimethylglycine) [acidifier], 1 mg magnesium l-threonate [stabilizer].

OTHER EXCIPIENTS: "Annatto color" (as a blend of annatto with stomach substance [thickener/stabilizer]) [colorant], citrates (citric, sodium) [stabilizers], flavin adenine dinucleotide 8 (FAD), gelatin (bovine), glycerine, plant lipids (sunflower) [lecithin], natural orange flavor [masking], nicotinamide adenine dinucleotide hydride 8 (NADH), pyridoxal 5' phosphate 8 (P5P), piperine [bioavailability enhancer], purified water, thiamine pyrophosphate 8 , ubidecarenone [antioxidant], yellow beeswax.

⁵ 20% daily value (DV) of VITAMIN C, and 5% DV IRON for pregnancy

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:

Vitamin B₁₂ [**TREATMENT**]; FOLATE [*PREVENTION*]; OTHER [*SUPPLEMENTATION*];

INDICATIONS:

EnBrace® HR is indicated in the TREATMENT of vitamin deficiency - specifically vitamin B₁₂ deficiency, and the PREVENTION of vitamin B₁₂-cofactor deficiency, l-methylfolate.

Requirements of vitamin B₉ and/or vitamin B₁₂ in excess of normal due to pregnancy can usually be met with oral supplementation.

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 B₁₂ - although it may improve vitamin B₁₂-deficient megaloblastic anemia. Exclusive use of folic acid in treating vitamin B₁₂-deficient megaloblastic anemia could result in progressive and irreversible neurologic damage. Specifically, vitamin B₁₂ 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 B₁₂ 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 B₁₂ 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 vitamin B₁₂.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY:

There is no evidence from long-term use in patients with pernicious anemia that vitamin B₁₂ or folate is carcinogenic. Pernicious anemia is associated with increased incidence of carcinoma of the stomach, but this is believed to be related to the underlying pathology and not to treatment with vitamin B₁₂.

PREGNANCY, NURSING MOTHERS, PEDIATRIC USE:

Vitamin B₉ and vitamin B₁₂ are essential vitamins and requirements are increased during pregnancy. Amounts of vitamin B₉ and vitamin B₁₂ that are recommended by the Food and Nutrition Board, National Academy of Science - National Research Council for lactating women should be consumed during pregnancy.

Vitamin B₁₂ and vitamin B₉ appear in the milk of nursing mothers in concentrations which approximate the mother's vitamin B₁₂ and vitamin B₉ blood level. Amounts of vitamin B₁₂ that are recommended by the Food and Nutrition Board, National Academies of Science - National Research Council for lactating women should be consumed during lactation.

Intake in pediatric patients should be in the amount recommended by the Food and Nutrition Board, National Academy of Science - National Research Council.

ADVERSE REACTIONS:

Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, feeling of swelling of entire body may occur with administration of vitamin B₁₂.

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DOSAGE AND ADMINISTRATION:

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

As a general rule reticulocyte plasma count, folate and vitamin B₁₂ 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 imprint **ENL**.

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

KEEP OUT OF THE REACH OF CHILDREN.

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

MANUFACTURED FOR:

JayMac Pharmaceuticals, LLC; Sunset, LA 70584.

MANUFACTURED AND/OR PACKAGED IN USA/CANADA.

PATENTS:

US other patent applications pending.

TRADEMARKS:

EnBrace® HR is a registered mark of JayMac Pharmaceuticals. DeltaFolate™ is a use-trademark of JayMac Pharmaceuticals.

Revision (Dec 27, 2021)

PRINCIPAL DISPLAY PANEL:

EnBraceHR™

with DeltaFolate™

NDC 64661-**650**-30

Rx Only

Certified 3rd-party GLUTEN-FREE

[15 mg DFE Folate][50 mcg CBI][1.5 MG FeGC]

ANTI-ANEMIA PREPARATION

Low-IRON

JayMac Pharmaceuticals, LLC

SOFTGEL (30 ct BOTTLE)

Prescription Prenatal Vitamin For Therapeutic Use

DESCRIPTION: EnBrace® HR is an orally administered prescription PRENATAL vitamin for therapeutic use formulated for adult patients who are under specific and direct monitoring of a licensed medical practitioner. A recent study* suggested that EnBrace® HR might be a better prenatal vitamin choice for women desiring to become pregnant, and who may be concurrently receiving treatment for depression.

* ClinicalTrials.gov Identifier: NCT02676882, TrialName HR for Depression Treatment and Prevention in Women Trying to Conceive and Early Pregnancy; Sponsor: Massachusetts General Hospital.

INGREDIENTS:

Citrated folic acid, DHF+ (B ₉ -Provitamin)	1 mg ¹
Folic acid (B ₉ -vitamin)	2.5 mg ¹
Levomethylfolate (B ₉ & B ₁₂ -deficient)	5.23 mg ¹
Vitamin B ₁₂ (cobalamide)	50 mcg ²
FeSC (1.5 mg elemental iron from ferrous glycine cysteinate)	13.6 mg ⁴

FUNCTIONAL EXCIPIENTS: 25 mg ascorbates^{3,4} (24 mg magnesium l-ascorbate, 1 mg zinc l-ascorbate), 500 mcg betaine (trimethylglycine), flavin adenine dinucleotide⁵ (NADH), 1 mg magnesium l-threonate, 25 mcg nicotinamide adenine dinucleotide hydride⁶ (NADH), at least 23.33 mg phospholipid-omega 3 complex⁷ (marine lipids), 25 mcg pyridoxal 5' phosphate⁸ (PSP), 25 mcg thiamine pyrophosphate⁸.

OTHER EXCIPIENTS: Annatto (colorant), citrates (citric sodium) (stabilizers), gelatin (bovine), glycerine, plant lipids (sunflower) (lecithin), natural orange flavor (masking), piperine (bioavailability enhancer), purified water, ubiquinol (antioxidant), yellow beeswax.

¹ 6 mg DFE folate (vitamin B₉). ² The form most found in mammalian liver. ³ 9 mg DFE l-methylfolate magnesium (molar equivalent). ⁴ Pure amino acid, cysteinylated iron chelate. ⁵ 20% daily value (DV) of VITAMIN C, and 5% DV IRON for pregnancy. ⁶ NADH is a significant source of magnesium and zinc. ⁷ Contains at least 12 mg phosphatidylserine (PS) – of which approximately 6.4 mg as PS-DHA-C6, and less than 1% EPA (<800 mcg PS-EPA-C6). ⁸ Contains less than 2% (<25 mcg/mole) of vitamins B₆, B₁₂, and B₁₂.

ADVERSE REACTIONS: Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, feeling of swelling of entire body may occur with administration of vitamin B₁₂. Allergic sensitization has been reported following both oral and parenteral administration of vitamin B₁₂.

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

PRECAUTIONS: 0.1 mg or more of vitamin B₁₂ daily may obscure pernicious anemia in that the hematological remission may occur while neurological manifestations remain progressive. Exclusive use of vitamin B₁₂ in treating vitamin B₁₂-deficient macrocytic anemia could result in progressive and irreversible neurological damage. Specifically, vitamin B₁₂ deficiency allowed to progress over 3 months may produce permanent degenerative lesions of the spinal cord – as observed when vitamin B₁₂ therapy is used as the only hematopoietic agent. Doses of vitamin B₁₂ exceeding 10 mcg daily may produce hematologic response in patients with vitamin B₁₂ deficiency. Indiscriminate administration may mask the true diagnosis. A dietary deficiency of only vitamin B₁₂ 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.

NDC 64661-650-30

Rx Only

with DeltaFolate™

EnBrace™ HR™

[15 mg DFE Folate] [50 mcg CBI] [1.5 mg Cys-Fe]

ANTI-ANEMIA PREPARATION
Low-IRON

JAYMAC
Pharmaceuticals, LLC

SOFTGEL (30 ct BOTTLE)

Prescription Prenatal Vitamin
For Therapeutic Use

INDICATION: EnBrace® HR is indicated in the TREATMENT of vitamin deficiency – specifically vitamin B₁₂ deficiency, and the PREVENTION of vitamin B₁₂-cofactor deficiency, l-methylfolate.

MECHANISM OF ACTION: VITAMIN B₁₂ (TREATMENT); FOLATE (PREVENTION); OTHER (SUPPLEMENTATION)

Vitamin B₁₂ is essential for the synthesis of methionine from homocysteine – a reaction which also requires l-methylfolate as a necessary cofactor. In the absence of vitamin B₁₂ – i.e., vitamin B₁₂ deficiency, tetrahydrofolate cannot be regenerated from l-methylfolate, and a functional vitamin B₁₂ deficiency occurs – i.e., “methyl trap hypothesis”. Gastrointestinal absorption of vitamin B₁₂ depends on the presence of sufficient intrinsic factor, and lack of intrinsic factor results in vitamin B₁₂ deficiency (i.e., pernicious anemia).

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

DOSE AND ADMINISTRATION: The adult dose, is one capsule daily preferably on an empty stomach. Do not exceed the recommended dose. Call your medical practitioner about side effects.

You may report side effects by calling 866-280-5961.

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

KEEP THIS OUT OF THE REACH OF CHILDREN. (Tamper Evident: Do not use if seal is broken or missing)

HOW SUPPLIED: EnBrace® HR is an oval, brownish-orange softgel capsule with imprint ENL.

REGULATORY: “Old” drugs, including vitamins, which were considered safe prior to 1938, were permitted to continue on the market without further review. However, FDA maintained the authority to review these old drugs if possible safety concerns became apparent. In 1951, the Durham-Humphrey Act was passed. This act formally differentiated between prescription and OTC drugs. – 44 FR 16131 (March 16, 1979).

JAYMAC Pharmaceuticals, LLC, Sunset, LA 70584, MANUFACTURED AND/OR PACKAGED IN USA/INDIA
Other U.S. Patents pending. **V22 (June 2022)**

3 64661 65030 2

ENBRACE HR

levomefolate magnesium, leucovorin, folic acid, ferrous cysteine glycinate, magnesium ascorbate, zinc ascorbate, cocarboxylase, flavin adenine dinucleotide, nadh, pyridoxal phosphate anhydrous, cobamamide, betaine, magnesium l-threonate, 1,2-docosahexanoyl-sn-glycero-3-phosphoserine calcium, 1,2-icosapentoyl-sn-glycero-3-phosphoserine calcium, and phosphatidyl serine capsule, delayed release pellets

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64661-650
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVOMEFOLATE MAGNESIUM (UNII: 1VZZ62R081) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	5.23 mg
LEUCOVORIN (UNII: Q573I9DVLP) (LEUCOVORIN - UNII:Q573I9DVLP)	LEUCOVORIN	2.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
FERROUS CYSTEINE GLYCINATE (UNII: 8B4OP7RK5N) (FERROUS CATION - UNII:GW895810WR)	FERROUS CYSTEINE GLYCINATE	13.6 mg
MAGNESIUM ASCORBATE (UNII: 0N1G678593) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	MAGNESIUM ASCORBATE	24 mg
ZINC ASCORBATE (UNII: 9TI35313XW) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ZINC ASCORBATE	1 mg
COCARBOXYLASE (UNII: Q57971654Y) (COCARBOXYLASE - UNII:Q57971654Y)	COCARBOXYLASE	25 ug
FLAVIN ADENINE DINUCLEOTIDE (UNII: ZC44YT18KK) (FLAVIN ADENINE DINUCLEOTIDE - UNII:ZC44YT18KK)	FLAVIN ADENINE DINUCLEOTIDE	25 ug
NADH (UNII: 4J24DQ0916) (NADH - UNII:4J24DQ0916)	NADH	25 ug

PYRIDOXAL PHOSPHATE ANHYDROUS (UNII: F06SGE49M6) (PYRIDOXAL PHOSPHATE ANHYDROUS - UNII:F06SGE49M6)	PYRIDOXAL PHOSPHATE ANHYDROUS	25 ug
COBAMAMIDE (UNII: F0R1QK73KB) (COBAMAMIDE - UNII:F0R1QK73KB)	COBAMAMIDE	50 ug
BETAINE (UNII: 3SCV180C9W) (BETAINE - UNII:3SCV180C9W)	BETAINE	500 ug
MAGNESIUM L-THREONATE (UNII: 1Y26ZZ00TM) (THREONIC ACID, DL- - UNII:NTD0MI8XRT)	MAGNESIUM L-THREONATE	1 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

Inactive Ingredients

Ingredient Name	Strength
ANNATTO (UNII: 6PQP1V1B6O)	
GELATIN (UNII: 2G86QN327L)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
PIPERINE (UNII: U71XL721QK)	
WATER (UNII: 059QF0K00R)	
UBIDECARENONE (UNII: EJ27X76M46)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

Product Characteristics

Color	BROWN (ANNATTO)	Score	no score
Shape	CAPSULE (oval)	Size	14mm
Flavor		Imprint Code	ENL
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64661-650-30	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 Pharma (830767260)

Registrant - Jaymac Pharma (830767260)

Establishment

Name	Address	ID/FEI	Business Operations
Ocean Healthcare Pvt Ltd		873673519	manufacture(64661-650)

Revised: 12/2023

Jaymac Pharma