

**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 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.*

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**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 direct monitoring of a licensed medical practitioner.

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

**INGREDIENTS:**

Folic acid, DHF+ (B<sub>9</sub>-Provitamin) . . . . . (1.7 mg DFE) 1 mg

Folinic acid (B<sub>9</sub>-vitamer). . . . . (4.25 mg DFE) 2.5 mg

Levomefolic acid (B<sub>9</sub> & B<sub>12</sub>- cofactor) . . . . . (9 mg DFE) 5.23 mg

Vitamin B<sub>12</sub> [cobamamide] . . . . .50  
mcg<sup>1</sup>

FeGC (1.5 mg elemental iron from ferrous glycine cysteinate) . . . . . 13.6 mg<sup>2,3</sup>

FUNCTIONAL EXCIPIENTS: 25 mg ascorbates<sup>3,4</sup> (24 mg magnesium l-ascorbate, 1 mg zinc l-ascorbate), 500 mcg betaine (trimethylglycine), flavin adenine dinucleotide<sup>6</sup> (FAD), 1 mg magnesium l-threonate, 25 mcg nicotinamide adenine dinucleotide hydride<sup>6</sup> (NADH), at least 23.33 mg phospholipid-omega 3 complex<sup>5</sup> [marine lipids], 25 mcg pyridoxal 5' phosphate<sup>6</sup> (P5P), 25 mcg thiamine pyrophosphate<sup>6</sup>.

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

*<sup>1</sup> The form most found in mammalian liver. <sup>2</sup> Pure amino acid, cysteinated iron chelate. <sup>3</sup> 20% Daily Value (DV) of VITAMIN C, and 5% DV IRON for pregnancy. <sup>4</sup> NOT a significant source of magnesium and zinc. <sup>5</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>6</sup> Contains less than 2% (<25 mcg/each) of vitamins B<sub>1</sub>, B<sub>2</sub>, B<sub>3</sub>, and B<sub>6</sub>.*

## **MECHANISM OF ACTION:**

Vitamin B<sub>12</sub> [**TREATMENT**]; FOLATE [*PREVENTION*]; OTHER [*SUPPLEMENTATION*];

## **INDICATIONS:**

**EnBrace HR<sup>®</sup>** 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.

*Requirements of vitamin B<sub>9</sub> and/or vitamin B<sub>12</sub> 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 B<sub>12</sub> - although it may improve vitamin B<sub>12</sub>-deficient megaloblastic anemia. Exclusive use of folic acid in treating vitamin B<sub>12</sub>-deficient megaloblastic anemia could result in progressive and irreversible neurologic damage. Specifically, vitamin B<sub>12</sub> 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<sub>12</sub> 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<sub>12</sub> 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 B<sub>12</sub>.

#### CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY:

There is no evidence from long-term use in patients with pernicious anemia that vitamin B<sub>12</sub> 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 B<sub>12</sub>.

#### PREGNANCY, NURSING MOTHERS, PEDIATRIC USE:

Vitamin B<sub>9</sub> and vitamin B<sub>12</sub> are essential vitamins and requirements are increased during pregnancy. Amounts of vitamin B<sub>9</sub> and vitamin B<sub>12</sub> 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 B<sub>12</sub> and vitamin B<sub>9</sub> appear in the milk of nursing mothers in concentrations which approximate the mother's vitamin B<sub>12</sub> and vitamin B<sub>9</sub> blood level. Amounts of vitamin B<sub>12</sub> 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 B<sub>12</sub>.

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

#### **DOSAGE AND ADMINISTRATION:**

The recommended dosage is one (1) capsule daily, preferably on an empty stomach. Dosage may be adjusted by a healthcare provider based on individual patient needs.

*As a general rule reticulocyte plasma count, folate and vitamin B<sub>12</sub> status must be obtained prior to treatment.*

**Do not exceed the recommended dose. Call your medical practitioner about side effects. You may report side effects by calling (866) 280-5961.**

#### **HOW SUPPLIED:**

Oval, brownish-orange softgel capsule with imprint **ENL**.

**STORAGE:**

Store at 20°-25°C (68°-77°F). *Protect from light and moisture.*

**Rx ONLY**

**KEEP OUT OF THE REACH OF CHILDREN.**

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

**MANUFACTURED FOR:**

JayMac Pharmaceuticals, LLC; Sunset, LA 70584.

MANUFACTURED IN INDIA / PACKAGED IN USA

**PATENTS:**

Patent applications pending.

**TRADEMARKS:**

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

**Revision** (*February 4, 2026*)

**PRINCIPAL DISPLAY PANEL:**

**EnBrace HR®**

*with DeltaFolate™*

NDC 64661-**650**-30

**Rx Only**

**[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<sup>1</sup> 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.  
<sup>1</sup> ClinicalTrials.gov Identifier: NCT02676882, "EnBrace HR for Depression Treatment and Prevention in Women Trying to Conceive and Early Pregnancy"; Sponsor: Massachusetts General Hospital.

**INGREDIENTS:**  
 Folic acid (DFE† [B-9 Provitamin]) ..... (1.7 mg DFE) 1 mg  
 Folic acid (B-9 vitamin) ..... (4.25 mg DFE) 2.5 mg  
 Levomefolic acid (B-9 & B-12 cofactor) ..... (9 mg DFE) 5.23 mg  
 Vitamin B-12 (cobalamin) ..... 50 mcg†  
 Fe/C (1.5 mg elemental iron from ferrous glycine cysteinate) ..... 13.6 mg<sup>2</sup>

**FUNCTIONAL INGREDIENTS:** 25 mg ascorbates<sup>3,4</sup> (24 mg magnesium l-ascorbate, 1 mg zinc-l-ascorbate), 500 mcg betaine (N-methylglycine), flavin adenine dinucleotide (FAD), 1 mg magnesium l-threonate, 25 mcg nicotinamide adenine dinucleotide hydride<sup>5</sup> (NADH), at least 23.33 mg phospholipid-omega 3 complex<sup>6</sup> (marine lipids), 25 mcg pyridoxal 5' phosphate (P5P), 25 mcg thiamine pyrophosphate<sup>7</sup>.

**OTHER EXCIPIENTS:** Anethole (solvent), citric acid, sodium lauryl sulfate, gelatin (bovine), glycerine, plant lipid (sunflower) (lecithin), natural orange flavor (masking), piperine (bioavailability enhancer), purified water, xanthan gum (antioxidant), yellow beeswax.

<sup>1</sup>The form most found in maternal liver. <sup>2</sup>Pure anemic acid, cyclized iron chelate. <sup>3</sup>20% Daily Value (DV) of Vitamin C, and 3% DV DV for pregnancy. <sup>4</sup>100% significant source of magnesium and zinc. <sup>5</sup> Contains at least 12 mg phosphatidylserine (PS) - of which approximately 6 mg is PS-DNA-Ca, and less than 1% EPA. (<800 mcg PS-EPA-Ca). <sup>6</sup>Contains less than 2% (25 mg) of vitamin B-6, B-12, and B-9.

**ADVERSE REACTIONS:** Mild transient diarrhea, polyphemia 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-12.  
**Warnings:** sensitization has been reported following both oral and parenteral administration of folic acid.  
**PRECAUTIONS:** 0.1 mg or more of vitamin B-12 daily may obscure pernicious anemia in that the hematological remission may occur while neurological manifestations remain progressive. Exclusive use of vitamin B-12 in treating vitamin B-12 deficient macrocytic anemia could result in progressive and irreversible neurological damage. Specifically, vitamin B-12 deficiency alone can progress over 3 months to cause permanent degenerative lesions of the spinal cord - as observed when vitamin B-12 therapy is used as the only hematopoietic agent. Doses of vitamin B-12 exceeding 10 mcg daily may produce hematologic response in patients with vitamin B-12 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 served in follow-up is the final criterion for adequacy of therapy.

NDC 64661-650-30

Rx Only



ANTI-ANEMIA PREPARATION

LOW-IRON



SOFTGEL (30 ct BOTTLE)

Prescription Prenatal Vitamin  
For Therapeutic Use

**INDICATION:** EnBrace HR® 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. In the absence of vitamin B-12, vitamin B-12 deficiency, tetrahydrofolate cannot be regenerated from l-methylfolate, and a functional vitamin B-12 deficiency occurs, "methyl trap hypothesis". Gastrointestinal absorption of vitamin B-12 depends on the presence of sufficient intrinsic factor, and lack of intrinsic factor results in vitamin B-12 deficiency (i.e. pernicious anemia).

**CONTAINS FISH/KRILL/SHOY:** No artificial colors. No dairy, wheat, sugar or egg.

**DOSEAGE AND ADMINISTRATION:** The recommended dosage is one (1) capsule daily, preferably on an empty stomach. Dosage may be adjusted by a healthcare provider based on individual patient needs.  
 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 IN INDIA / PACKAGED IN USA  
 U.S. Patents pending V26 (Feb 2026)



## 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

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LEVOMEFOLATE MAGNESIUM</b> (UNII: 1VZZ62R081) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	5.23 mg
<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>FERROUS CYSTEINE GLYCINATE</b> (UNII: 8B40P7RK5N) (FERROUS CATION - UNII:GW895810WR)	FERROUS CYSTEINE GLYCINATE	13.6 mg
<b>MAGNESIUM ASCORBATE</b> (UNII: 0N1G678593) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	MAGNESIUM ASCORBATE	24 mg
<b>ZINC ASCORBATE</b> (UNII: 9TI35313XW) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ZINC ASCORBATE	1 mg
<b>COCARBOXYLASE</b> (UNII: Q57971654Y) (COCARBOXYLASE - UNII:Q57971654Y)	COCARBOXYLASE	25 ug
<b>FLAVIN ADENINE DINUCLEOTIDE</b> (UNII: ZC44YT18KK) (FLAVIN ADENINE DINUCLEOTIDE - UNII:ZC44YT18KK)	FLAVIN ADENINE DINUCLEOTIDE	25 ug
<b>NADH</b> (UNII: 4J24DQ0916) (NADH - UNII:4J24DQ0916)	NADH	25 ug
<b>PYRIDOXAL PHOSPHATE ANHYDROUS</b> (UNII: F06SGE49M6) (PYRIDOXAL PHOSPHATE ANHYDROUS - UNII:F06SGE49M6)	PYRIDOXAL PHOSPHATE ANHYDROUS	25 ug
<b>COBAMAMIDE</b> (UNII: FOR1QK73KB) (COBAMAMIDE - UNII:FOR1QK73KB)	COBAMAMIDE	50 ug
<b>BETAINE</b> (UNII: 3SCV180C9W) (BETAINE - UNII:3SCV180C9W)	BETAINE	500 ug
<b>MAGNESIUM L-THREONATE</b> (UNII: 1Y26ZZ00TM) (THREONIC ACID, DL- - UNII:NTD0MI8XRT)	MAGNESIUM L-THREONATE	1 mg
<b>1,2-DOCOSAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM</b> (UNII: 6VJM73T46K) (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

### Inactive Ingredients

Ingredient Name	Strength
<b>ANNATTO</b> (UNII: 6PQP1V1B6O)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)	
<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>	CAPSULE (oval)	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	ENL
<b>Contains</b>			

### 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 Pharmaceuticals, LLC (830767260)

**Registrant** - Jaymac Pharmaceuticals, LLC (830767260)

### Establishment

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