

**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™**  
**Multiphasic Soft Gelatin Capsules**

**EnBrace® HR**  
*with DeltaFolate™*

**[15 mg DFE Folate ] [50 mcg CBl] [1.5 mg FeGC]**

**ANTI-ANEMIA PREPARATION** *as folate, cobalamin & low-iron*

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

*Multi-phasic Capsules (30ct bottle)*

NDC 64661-650-30

**R x Only [DRUG]**

**GLUTEN-FREE**

#### **DESCRIPTION:**

**EnBrace® HR** is an orally administered prescription prenatal vitamin drug for therapeutic use formulated to meet the unique nutritional needs of pregnancy - regardless of lactation status. **EnBrace® HR** may be taken by female macrocytic anemia patients that are in need of treatment and are under specific direction and monitoring of vitamin B<sub>9</sub> and vitamin B<sub>12</sub> status by a physician.

***EnBrace® HR** is intended for women of childbearing age, and may be prescribed for women at risk of folate or cobalamin deficiency - including folate-induced perinatal and postpartum depression, and are at risk of folate-induced birth defects such as may be found with spina bifida and other neural tube defects (NTDs).*

**EnBrace® HR** is intended to address the increased need for metabolically-active variants of vitamin B<sub>9</sub>-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). **EnBrace® HR** achieves this through passive diffusion of these different biologically-active vitamers.

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

#### **INGREDIENTS:**

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Control-release, citrated folic acid, DHF+ (B <sub>9</sub> - Provitamin)	1 mg <sup>1</sup>
Vitamin B <sub>12</sub> [cobamamide]	50 mcg <sup>2</sup>
FeGC [ferrous glycine cysteinate] (1.5 mg elemental iron)	13.6 mg <sup>3</sup>

**ALSO CONTAINS:**

Folinic acid (B <sub>9</sub> -vitamer)	2.5 mg <sup>1</sup>
Levomefolic acid (B <sub>9</sub> & B <sub>12</sub> - cofactor)	5.23 mg <sup>4</sup>

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<sup>1</sup> 6 mg DFE folate (vitamin B<sub>9</sub>)

<sup>2</sup> The form most found in mammalian liver - adjusted for stability and pH in the presence of stomach substance, is a cobamamide, or vitamin B<sub>12</sub>

<sup>3</sup> Pure amino acid, cysteinated iron chelate as AminoFerTM\* under exclusive license

<sup>4</sup> 9 mg DFE l-methylfolate magnesium (molar equivalent)

\* AminoFerTM (Viva Pharmaceuticals, Canada) U.S. Patent # 7,341,708

FUNCTIONAL EXCIPIENTS: 25 mg ascorbates<sup>5,6</sup> (24 mg magnesium l-ascorbate, 1 mg zinc l-ascorbate) [antioxidant], at least 23.33 mg phospholipid-omega 3 complex<sup>7</sup> [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 <sup>8</sup> (FAD), gelatin (bovine), glycerine, plant lipids (sunflower) [lecithin], natural orange flavor [masking], nicotinamide adenine dinucleotide hydride <sup>8</sup> (NADH), pyridoxal 5' phosphate <sup>8</sup> (P5P), piperine [bioavailability enhancer], purified water, thiamine pyrophosphate <sup>8</sup>, ubidecarenone [antioxidant], yellow beeswax.

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

<sup>6</sup> NOT a significant source of magnesium and zinc

<sup>7</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>8</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>

### **CONTAINS FISH/KRILL/SOY.**

*Certified 3rd-party GLUTEN-FREE. No artificial colorants. No dairy, wheat, sugar or egg.*

### **MECHANISM OF ACTION:**

**Vitamin B<sub>9</sub>** [treatment]; **Vitamin B<sub>12</sub>** [prevention]; and **Iron** [prophylactic].

[Vitamin B<sub>9</sub>]

Vitamin B<sub>9</sub> deficiency results in megaloblastic anemia. Vitamin B<sub>9</sub> stimulates specifically the production of red blood cells, white blood cells, and platelets in persons suffering from certain megaloblastic anemias.

Folic acid, folinic acid and l-methylfolate metabolism results in the creation of tetrahydrofolic acid by different pathways. Both folinic acid and levomefolic acid do not require dihydrofolate reductase (DHR), however folic acid does.

[Vitamin B<sub>12</sub>]

Vitamin B<sub>12</sub> 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. Vitamin B<sub>12</sub> has hematopoietic activity apparently identical to that of the anti-anemia factor in purified liver extract.

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:

**EnBrace® HR** is indicated in the treatment of folate-induced macrocytic anemias before, during or after pregnancy including megaloblastic anemias, and the prevention of cobalamin deficiency.

*Requirements of vitamin B<sub>9</sub> and/or vitamin B<sub>12</sub> 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 vitamin B<sub>12</sub>, 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.**
- The parenteral administration of (cyano)cobalamin – or vitamin B<sub>12</sub>, 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<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 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 "ENL"<sup>9</sup> on one side, in bottles of 30 with NDC 64661-650-30.

#### **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.**

<sup>9</sup>Upper 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:

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

Revision 3(April 2019)

## PRINCIPAL DISPLAY PANEL:

NDC 64661-650-30

Rx Only

Certified 3rd-party GLUTEN-FREE

WITH DeltaFolate™ EnBrace™ HR™

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

ANTI-ANEMIA PREPARATION

as folate, cobalamin & low-iron

JAYMAC

Pharmaceuticals, LLC

SOFTGEL (30 ct BOTTLE)

Prescription Prenatal/Vitamin Drug

For Therapeutic Use

**DESCRIPTION:** EnBrace® HR is an orally administered prescription prenatal vitamin drug for therapeutic use formulated to meet the unique nutritional needs of pregnancy – regardless of lactation status. EnBrace® HR may be taken by female macrocytic anemia patients that are in need of treatment, and are under specific direction and monitoring of vitamin B9 and vitamin B12 status by a physician. EnBrace® HR, through passive diffusion of folate-vitamins, is intended to address the increased need for metabolically-active forms of folate in the cerebrospinal fluid, plasma, and for red blood cells in patients with MTHFR (at alleles C607T, A1298C and/or G1793A) and/or p53-pregnancy, pregnancy and/or post-pregnancy – regardless of lactation status, patients. EnBrace® HR is intended for women of childbearing age, and may be prescribed for women at risk of folate or cobalamin deficiency – including folate-induced perinatal and postpartum depression, and are at risk of folate-induced birth defects such as may be found with spina bifida and other neural tube defects (NTDs). EnBrace® HR contains a small amount of iron and may be taken concurrently with iron supplementation.

**INDICATION:** EnBrace® HR is indicated in the treatment of folate-induced macrocytic anemias before, during or after pregnancy – including megaloblastic anemias, and the prevention of cobalamin deficiency.

**INGREDIENTS:**  
 Control-release, enteric coated folic acid, DHF+ (B<sub>9</sub>-Provitamin) ..... 1 mg<sup>1</sup>  
 Vitamin B<sub>12</sub> (cobalamine) ..... 50 mcg<sup>2</sup>  
 FeGC (ferrous glycine cysteinylate) (1.5 mg elemental iron) ..... 13.6 mg<sup>3</sup>

**ALSO CONTAINS:**  
 Folic acid (B<sub>9</sub>-vitamin) ..... 2.5 mg<sup>1</sup>  
 Levomefolate acid (B<sub>9</sub> & B<sub>12</sub> cofactor) ..... 5.23 mg<sup>4</sup>  
 1 mg DFE folate (vitamin B<sub>9</sub>)  
 2 The form most found in mammalian liver – adjusted for stability and pH in the presence of stomach substance, is a cobalamine, or vitamin B<sub>12</sub>  
 3 Pure amino acid, cyclized iron chelate as Amvator™™ under exclusive license  
 4 9 mg DFE(1-methyltetrahydrofolate) (methyl equivalent)  
 \* Amvator™™ (NivePharmaceuticals, Canada) U.S. Patent # 7,341,700

**FUNCTIONAL EQUIVALENTS:** 25 mg ascorbates 56 (24 mg magnesium l-ascorbate, 1 mg zinc l-ascorbate) [antioxidant], at least 23.33 mg phospholipid-omega 3 complex [marine lipids], 500 mcg betaine (trimethylglycine) [acidifier], 1 mg magnesium l-threonate [stabilizer].

**OTHER INGREDIENTS:** "Anatto color" (asa leaf of annatto with stomach substance [thickener/stabilizer] [colorant], citrate [acid], sodium [stabilizer], flavin adenine dinucleotide (FAD), germin [bitter], glycine, plant lipids [softener] [essential], natural orange flavor [masking], ascorbic acid, ascorbic acid, ascorbic acid, hydroxyethylcellulose (HCE), pyridoxal phosphate (P5P), piperine [bioavailability enhancer], purified water, thiazine phosphosphate, ubiquinolone [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-Ga, and less than 1% BH  
 8 Contains less than 2% (<25 mg each) of vitamins B1, B2, B3 and B6.

NDC 64661-650-30 Rx Only  
 Certified 3rd-party GLUTEN-FREE  
 with DeltaFolate™  
**EnBrace™ HR™**  
 [15 mg DFE Folate] [50 mcg CBI] [1.5 mg FeGC]  
 ANTI-ANEMIA PREPARATION  
 as folate, cobalamin & low-iron  
**JAYMAC**  
 Pharmaceuticals, LLC  
 SOFTGEL (30 ct BOTTLE)  
 Prescription Prenatal/Vitamin Drug  
 For Therapeutic Use

**CONTAINS FISH/KRILL/SOY.** Certified 3rd-party GLUTEN-FREE. No artificial colorants. No dairy, wheat, sugar or egg.  
**WARNING: 1. USE OF THIS PRODUCT WITHOUT DIRECT SUPERVISION OF A PHYSICIAN IS DANGEROUS.** 2. Some patients afflicted with pernicious anemia may or may not respond to the orally ingested vitamin B<sub>12</sub>, and there is no known way to predict which patients may respond and which patients may cease to respond. 3. Periodic examinations and laboratory studies of pernicious anemia patients are essential and recommended. 4. The parenteral administration of (cyanocobalamin- or vitamin B<sub>12</sub>) is generally recognized as a fully effective treatment of pernicious anemia. Parenteral allyl-cobalamin preparations have not been and are not authorized for use except by or on the prescription of a physician.

**DOSAGE 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:** Oral, brownish-orange softgel capsule with "ENL" on one side.  
**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.  
**PRECAUTIONS:** 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).  
 JAYMAC Pharmaceuticals, LLC, Sunset, LA 70584  
 MANUFACTURED AND/OR PACKAGED IN USA/CANADA  
 U.S. Patent # 7,341,708; and other patents pending. Rev April, 2019

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: 059QF0KO0R)	
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
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1	NDC:64661-650-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/12/2011	
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## 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)

Revised: 6/2019

JAYMAC Pharmaceuticals, LLC