

**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.*

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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 directr monitoring of a licensed medical practitioner.

***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>
<b>ALSO CONTAINS:</b>	
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 AminoFer™\* under exclusive license

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

\* AminoFer™ (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 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.

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

### **INDICATIONS:**

**EnBrace® HR** 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 adult dose is one capsule daily *preferably on an empty stomach*.

*As a general rule reticulocyte plasma count, folate and vitamin B<sub>12</sub> 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, "EnBrace HR for Depression Treatment and Prevention in Women Trying to Conceive and Early Pregnancy"; Sponsor: Massachusetts General Hospital.

**INGREDIENTS:**

Citrated folic acid, DHF+ (B<sub>9</sub>-Provitamin) ..... 1 mg<sup>1</sup>  
 Folic acid (B<sub>9</sub>-vitamin) ..... 2.5 mg<sup>1</sup>  
 Levomefolic acid (B<sub>9</sub> & B<sub>12</sub>-deficient) ..... 5.23 mg<sup>3</sup>  
 Vitamin B<sub>12</sub> (cobamide) ..... 25 mcg<sup>2</sup>  
 FeC (1.5 mg elemental iron from ferrous glycine cysteinate) ..... 13.6 mg<sup>4</sup>

**FUNCTIONAL EXCIPIENTS:** 25 mg ascorbates<sup>5-8</sup> (24 mg magnesium l-ascorbate, 1 mg zinc l-ascorbate), 500 mcg betaine (trimethylglycine), flavin adenine dinucleotide-<sup>9</sup> (NAD), 1 mg magnesium l-threonate, 25 mcg nicotinamide adenine dinucleotide hydrate<sup>4</sup> (NADH), at least 23.33 mg phospholipid-omega 3 complex<sup>7</sup> (marine lipids), 25 mcg pyridoxal 5' phosphate<sup>4</sup> (P5P), 25 mcg thiamine pyrophosphate<sup>4</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, ubiquinolone (antioxidant), yellow beeswax.

<sup>1</sup> 6 mg DFE folate (vitamin B<sub>9</sub>). <sup>2</sup> The form most found in mammalian liver. <sup>3</sup> 9 mg DFE l-methylfolate magnesium (molar equivalent). <sup>4</sup> Pure amino acid, cysteinated iron chelate. <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 total) of vitamins B<sub>6</sub>, B<sub>9</sub> and B<sub>12</sub>.

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

**PRECAUTIONS:** 0.1 mg or more of vitamin B<sub>9</sub> daily may obscure pernicious anemia in that the hematological remission may occur while neurological manifestations remain progressive. Exclusive use of vitamin B<sub>9</sub> in treating vitamin B<sub>12</sub>-deficient macrocytic anemia could result in progressive and irreversible neurological 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 vitamin B<sub>9</sub> therapy is used as the only hematopoietic agent. Doses of vitamin B<sub>9</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. 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.

NDC 64661-650-30

**Rx Only**



**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 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. In the absence of vitamin B<sub>12</sub> – i.e., vitamin B<sub>12</sub> deficiency, tetrahydrofolate cannot be regenerated from l-methylfolate, and a functional vitamin B<sub>9</sub> deficiency occurs – i.e., "methyl trap hypothesis". Gastrointestinal absorption of vitamin B<sub>12</sub> depends on the presence of sufficient intrinsic factor, and lack of intrinsic factor results in vitamin B<sub>12</sub> deficiency (i.e., pernicious anemia).

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

**DOSEAGE 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)**



## ENBRACE HR

levomefolate magnesium, leucovorin, folic acid, ferrous cysteine glycinate, magnesium ascorbate, zinc ascorbate, cocarboxylase, flavin adenine dinucleotide, nadh, pyridoxal phosphate anhydrous, cobamide, 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:GW89581OWR)	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: F0R1QK73KB) (COBAMAMIDE - UNII:F0R1QK73KB)	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: 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

## 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 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