

**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.*

-----  
**EnBrace HR™**  
**Multiphasic Soft Gelatin Capsules**

**EnBrace® HR**  
*with DeltaFolate™*

*[50 mcg B<sub>12</sub>] [15 mg DFE Folate]*

**ANTI-PERNICIOUS ANEMIA B<sub>12</sub>-PREPARATION** *with 9mg DFE l-methylfolate magnesium and 6mg DFE other folates.*

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

*Multi-phasic Capsules (30ct bottle)*

**NDC 64661-650-30**

**R<sub>x</sub> Only [DRUG]**

**GLUTEN-FREE**

## **DESCRIPTION:**

**EnBrace® HR** is an orally administered prescription prenatal/**vitamin drug** *for therapeutic use* formulated for female macrocytic anemia patients that are in need of treatment, and are under specific direction and monitoring of vitamin B<sub>12</sub> status by a physician. *EnBrace® HR is intended for women of childbearing age who are – or desire to become, pregnant.*

## **INGREDIENTS**

Adenosylcobalamin (coenzyme B12)	50 mcg
Formyltetrahydrofolic acid (B9-vitamer)	2.5 mg*
Folic acid, DHF - (provitamin B9)	1 mg <sup>†</sup> *
Levomefolic acid, magnesium salt (B12 cofactor)	7 mg <sup>†</sup>

\* 6 mg DFE folate (vitamin B9) of at least 15 mg DFE total folate

† From 9 mg l-methylfolate (molar equivalent)

**FUNCTIONAL EXCIPIENTS:** 13.6 mg FeGC as ferrous glycine cysteinate (1.5 mg elemental iron<sup>3</sup>) [colorant], 25 mg ascorbates<sup>1,2</sup> (24 mg magnesium l-ascorbate, 1 mg zinc l-ascorbate) [antioxidant], at least 23.33 mg phospholipid-omega3 complex<sup>3</sup> [marine lipids], 500 mcg betaine (trimethylglycine) [acidifier], 1 mg magnesium l-threonate [stabilizer].

**OTHER EXCIPIENTS:** Annatto [colorant], citrates (citric, sodium) [stabilizers], flavin adenine dinucleotide<sup>4</sup> (FAD), gelatin (bovine), glycerine, plant lipids (sunflower) [lecithin], natural orange flavor [masking], nicotinamide adenine dinucleotide hydride<sup>4</sup> (NADH), pyridoxal 5 phosphate<sup>4</sup> (P5P), piperine [bioavailability enhancer], purified water, thiamine pyrophosphate<sup>4</sup>, ubidecarnone [antioxidant], yellow

beeswax.

**CONTAINS FISH/KRILL/SOY.**

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

- 
- 1 20% daily value (DV) of VITAMIN C, and 5% DV IRON.
  - 2 NOT a significant source of magnesium and zinc.
  - 3 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)
  - 4 Contains less than 2% (<25 mcg/each) of vitamins B1, B2, B3 and B6.

**MECHANISM OF ACTION**

*Vitamin B<sub>12</sub>[active]; Folate[prophylactic]*

**INDICATIONS**

**EnBrace® HR** is indicated in the treatment of pernicious anemias of pregnancy, and prophylactic folate supplementation.

**WARNING**

- 
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.**
  4. 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**

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 vitamin folic acid is 1 mg.

**ADVERSE REACTIONS**

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*.

**Do not exceed 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 ENL<sup>5</sup> on one side, in bottles of 30 with NDC 64661-650-30.

---

<sup>5</sup> Upper case

## 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.*

**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 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.

*Rev August 2017*

## PRINCIPAL DISPLAY PANEL

**NDC 64661-650-30**

**R<sub>x</sub> Only**

***EnBrace™HR™***

**[50 mcg B<sub>12</sub> ] [15 mg DFE folate]**

**ANTI-PERNICIOUS ANEMIA B12-PREPARATION**

with 9mg DFE l-methylfolate magnesium and 6mg DFE other folates

**JAYMAC**

*Pharmaceuticals, LLC*

**30 ct. Softgels • Dye and Gluten Free**

**Enhanced Prenatal  
Vitamin Supplement**

**INGREDIENTS** Each oval, brownish-orange softgel with imprint "ENL" contains:  
 Vitamin B<sub>12</sub> (cobalamide) ..... 50 mcg

**ALSO CONTAINS:**  
 L-methylfolate..... 5.23 mg<sup>1</sup>  
 Folic acid..... 2.5 mg<sup>2</sup>  
 Folic acid, DHP<sup>3</sup> (control released/citrated)..... 1 mg<sup>4</sup>

<sup>1</sup> 15 mg DFE (dietary folate equivalents) total folate comprised of 9 mg DFE L-methylfolate magnesium and 6 mg DFE other folates.

**FUNCTIONAL EXCIPIENTS:** 13.6 mg FeCl<sub>2</sub> as ferrous glycine (1.5 mg elemental iron) (colorant), 25 mg ascorbates<sup>5</sup> (24 mg magnesium L-ascorbate, 1 mg zinc L-ascorbate), at least 23.33 mg phospholipid omega-3 complex<sup>6</sup> (at least), 500 mg betaine (betamethylglycine) (acidifier), 1 mg magnesium L-threonate (stabilizer).

**OTHER EXCIPIENTS:** Annatto (colorant), citric acid (citric sodium) (stabilizers), FAD<sup>8</sup>, oleanin (bovine), glycerine, plant lipids (sunflower) (lecithin), natural orange flavor (masking), NADH<sup>9</sup>, PVP<sup>10</sup>, piperine (bioavailability enhancer), purified water, thiamine pyrophosphate<sup>11</sup>, stibocamane (antioxidant), yellow beeswax.


**CONTAINS FISH/KRILL/SOY** Certified 3rd-Party Gluten-Free. No artificial colorants. No dairy, wheat, sugar or eggs.

**ADVERSE REACTIONS:** Allergic sensitization has been reported following both oral & parenteral administration of vitamin B<sub>12</sub>.

**PRECAUTIONS:** 0.1 mg or more of vitamin B<sub>12</sub> daily may obscure pernicious anemia in that the hematologic remission may occur while neurological manifestations remain progressive. The safe tolerable upper limit for vitamin B<sub>12</sub> is 1 mg.


<sup>2</sup> 20% daily value (DV) of VITAMIN C, and 5% DV of IRON.  
<sup>3</sup> NOT a significant source of magnesium and zinc.  
<sup>4</sup> Contain at least 12 mg PS of which approximately 6.4 mg as PS-DHA-Ca and less than 1% EPH (< 800 mcg PS-EPH-Ca).  
<sup>5</sup> Contains less than 2% (< 25 mg/each) of B<sub>1</sub>, B<sub>6</sub>, B<sub>12</sub> & B<sub>15</sub> as colorants.  
<sup>6</sup> Upper case  
**PATENTS:** U.S. Patents # 7,341,708; and other patents pending.

NDC 64661-650-30 **Rx Only**



**Enbrace HR™**  
 [50 mcg B<sub>12</sub>] [15 mg DFE folate]

**ANTI-PERNICIOUS ANEMIA B<sub>12</sub>-PREPARATION**  
 with 9mg DFE L-methylfolate magnesium and 6mg DFE other folates



Softgels (30 ct Bottle) - Dye and Gluten Free

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

**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 cause 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.


**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)

**DESCRIPTION:** Enbrace HR™ is an orally administered prescription prenatal/vitamin drug for therapeutic use formulated for female macrocytic anemia patients that are in need of treatment, and are under specific direction and monitoring of vitamin B<sub>12</sub> status by physician. Enbrace HR™ is intended for women of childbearing age who are - or desire to become pregnant.

**INDICATION:** Enbrace HR™ is indicated in the treatment of pernicious anemias of pregnancy, and prophylactic folate supplementation.

**CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION.**

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



**MANUFACTURED FOR: JAYMAC Pharmaceuticals, LLC, Sarat, LA 70584**  
 MANUFACTURED AND/OR PACKAGED IN USA/CANADA **Rev Aug 2017**

Lot:  
Exp:

## 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: 8B40P7RK5N) (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: 1Y26ZZ0OTM) (THREONIC ACID, DL - UNII:NTD0M18XRT)	MAGNESIUM L-THREONATE	1 mg	
1,2-DOCOAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE CALCIUM (UNII: 6WJM73T46K) (1,2-DOCOAHEXANOYL-SN-GLYCERO-3-PHOSPHOSERINE - UNII:DVY071LFIW)	1,2-DOCOAHEXANOYL-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)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
ORANGE (UNII: 5EVU04N5QU)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
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	04/08/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		04/08/2015	

**Labeler** - JAYMAC Pharmaceuticals, LLC (830767260)

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