OBSTETRIX EC- beta carotene, ascorbic acid, cholecalciferol, dl-alpha tocopheryl acetate, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, l-5-methyltetrahydrofolate calcium, cyanocobalamin, carbonyl iron, magnesium oxide, zinc oxide, sodium selenate tablet

## Obstetrix™ EC

Seyer Pharmatec, Inc.

Supplement Facts		
Serving Size: 1 Caplet / Servings Per		
Container: 60		
	Amount	-
	Per Serving	Value**
Vitamin A (as Beta Carotene)	810 mcg	62%
Vitamin C (as Ascorbic Acid)	120 mg	100%
Vitamin D (as Cholecalciferol)	10 mcg	67%
Vitamin E (as dl-Alpha Tocopheryl Acetate)	8.1 mg	43%
Thiamin (as Thiamine HCI)	3 mg	214%
Riboflavin	3.4 mg	213%
Niacin (as Niacinamide)	20 mg	111%
Vitamin B6 (as Pyridoxine HCl)	40 mg	2000%
Folate (as L-5-Methyltetrahydrofolate Calcium)	1700 mcg DFE	283%
	(1000 mcg Folic Acid)	
Vitamin B12 (as Cyanocobalamin)	12 mcg	429%
Iron (as Carbonyl Iron)	29 mg	107%
Magnesium (as Magnesium Oxide)	30 mg	8%
Zinc (as Zinc Oxide)	25 mg	192%
Selenium (as Sodium Selenate)	65mcg	93%
* Daily Value (DV) for Pregnant and Lactating Women.		

#### OTHER INGREDIENTS:

Microcrystalline Cellulose, Methacrylic Acid Copolymer, Croscarmellose Sodium, Gelatin, Stearic Acid, Hypromellose, Maltodextrin, Crospovidone, Starch, Silica, Titanium Dioxide, Triacetin, Sucrose, Citric Acid, Magnesium Stearate, Sodium Lauryl Sulfate, Polyvinylpyrrolidone, Soy Polysaccharide, Mineral Oil, Riboflavin, FD&C Yellow #6 Lake, Sodium Ascorbate, Polyethylene Glycol, Trisodium Citrate, Tocopherols, Tricalcium Phosphate, Glycerol Monostearate, Triethyl Citrate, Ascorbyl Palmitate, Triglycerides, Sodium Benzoate, Polysorbate 80, Sorbic Acid and Talc. Contains soy.

#### **DESCRIPTION:**

**OBSTETRIX™ EC** enteric coated prenatal caplets are a multivitamin/multi-mineral dietary supplement indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and non-lactating mothers.†

It is recommended that for all women folate levels should be high for at least one month prior to possible conception and continued at that level for the first three months of pregnancy.†

†These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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

One caplet daily or as directed by a physician.

#### **CONTRAINDICATIONS:**

**OBSTETRIX™ EC** is contraindicated in patients with a known hypersensitivity to any of the components of this product. Hemochromatosis and hemosiderosis are contraindications to iron therapy.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or Poison Control Center immediately.

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B-12 is deficient.

## **PRECAUTIONS:**

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. Pernicious anemia should be excluded before using this product since folic acid may mask the symptoms of pernicious anemia.

## **ADVERSE REACTIONS:**

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

#### STORAGE:

Store at room temperature, USP.

Keep out of the reach of Children.

To report a serious adverse event or to obtain product information, contact (888) 444-5072.

#### Manufactured in the USA for:

## Seyer Pharmatec, Inc. Caguas, Puerto Rico 00725

## DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

## **Dietary Supplement**

## **Enteric Coated Prenatal Caplets**

## with 100% Bioactive Folate

- Well tolerated
- Easy to swallow

## **Packaging**



## DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

# Supplement Facts Serving Size: 1 Caplet / Servings Per Container: 60

	Amount Per Serving	% Daily Value**	
Vitamin A (as Beta Carotene)	810 mcg	62%	
Vitamin C (as Ascorbic Acid)	120 mg	100%	
Vitamin D (as Cholecalciferol)	10 mcg	67%	
Vitamin E (as dl-Alpha Tocopheryl Aceta	te) 8.1 mg	43%	
Thiamin (as Thiamine HCI)	3 mg	214%	
Riboflavin	3.4 mg	213%	
Niacin (as Niacinamide)	20 mg	111%	
Vitamin B6 (as Pyridoxine HCI)	40 mg	2000%	
	700 mcg DFE cg Folic Acid)	283%	
Vitamin B12 (as Cyanocobalamin)	12 mcg	429%	
Iron (as Carbonyl Iron)	29 mg	107%	
Magnesium (as Magnesium Oxide)	30 mg	8%	
Zinc (as Zinc Oxide)	25 mg	192%	
Selenium (as Sodium Selenate)	65mcg	93%	
* Daily Value (DV) for Pregnant and Lactating Women.			

7 **9** Lot # & Exp

OTHER INGREDIENTS: Microcrystalline Cellulose, Methacrylic Acid Copolymer, Croscarmellose Sodium, Gelatin, Stearic Acid, Hypromellose, Maltodextrin, Crospovidone, Starch, Silica, Titanium Dioxide. Triacetin. Sucrose. Citric Acid. DESCRIPTION: OBSTETRIX™EC enteric coated prenatal caplets are a multivitamin/multi-mineral dietary supplement indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and non-lactating mothers.<sup>†</sup>

It is recommended that for all women folate levels should be high for at least one month prior to possible conception and continued at that level for the first three months of pregnancy.

<sup>†</sup>These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

**DOSAGE AND ADMINISTRATION:** One caplet daily or as directed by a physician.

**CONTRAINDICATIONS: OBSTETRIX™ EC** is contraindicated in patients with a known hypersensitivity to any of the components of this product. Hemochromatosis and hemosiderosis are contraindications to iron therapy.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or Poison Control Center immediately.

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B-12 is deficient.

PRECAUTIONS: Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can



occur while neurological manifestations remain progressive. Pernicious anemia should be excluded before using this product since folic acid may mask the symptoms of pernicious anemia.

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

STORAGE: Store at room temperature, USP.

Keep out of the reach of children.

To report a serious adverse event or to obtain product information, contact (888) 444-5072.

Code SEY2626-6L

Rev. 10/20

Manufactured in the USA for:



Seyer Pharmatec, Inc. Caguas, Puerto Rico 00725

## **OBSTETRIX EC**

beta carotene, ascorbic acid, cholecalciferol, dl-alpha tocopheryl acetate, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, l-5-methyltetrahydrofolate calcium, cyanocobalamin, carbonyl iron, magnesium oxide, zinc oxide, sodium selenate tablet

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:11026-2632
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	810 ug	
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg	
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug	
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHATOCOPHEROL, DL UNII:7QWA1RIO01)	.ALPHATOCOPHEROL, DL-	8.1 mg	
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	3 mg	
RIBOFLAVIN (UNII: TLM29760FR) (RIBOFLAVIN - UNII:TLM29760FR)	RIBOFLAVIN	3.4 mg	
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	20 mg	
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII: KV2JZ 1BI6Z)	PYRIDOXINE HYDROCHLORIDE	40 mg	

LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	1700 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	29 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	30 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 mg
SODIUM SELENATE (UNII: 5DQP25600A) (SELENATE ION - UNII:6X37R1DB70)	SELENIUM	65 ug

Inactive Ingredients	
Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
STARCH, CORN (UNII: 08232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
SUCROSE (UNII: C151H8M554)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POVIDONE K60 (UNII: SZR7Z3Q2YH)	
SOYBEAN COTYLEDON CELL WALL POLYSACCHARIDES (UNII: 4UL6DF56YQ)	
MINERAL OIL (UNII: T5L8T28FGP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SODIUM ASCORBATE (UNII: S033EH8359)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
SORBIC ACID (UNII: X045WJ989B)	
TALC (UNII: 7SEV7J4R1U)	

P	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NHRIC:11026-2632-6	60 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		02/14/2023	

**Supplement Facts** 

Serving Size : Serving per Container :

Amount Per Serving % Daily Value

color

shape

size (solid drugs) 13 mm

scoring 1

imprint

Labeler - Seyer Pharmatec, Inc. (832947126)

Revised: 2/2023 Seyer Pharmatec, Inc.