

**SELECT OB- .beta.-carotene, vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, levomefolate calcium, cobalamin, iron, magnesium oxide, and zinc oxide tablet, chewable Everett Laboratories, Inc.**

*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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**SELECT-OB® Chewable Caplets  
 Prenatal Supplement**

<b>Supplement Facts</b>		
<b>Serving Size 1 Caplet</b>		
<b>Each Caplet contains</b>	<b>% Daily Value</b>	
Vitamin A (as beta carotene and acetate)	1700 IU	21%
Vitamin C (as ascorbic acid)	60 mg	100%
Vitamin D (as cholecalciferol)	400 IU	100%
Vitamin E (as dl-alpha tocopheryl acetate)	30 IU	100%
Thiamin (Vitamin B1)	1.6 mg	94%
Riboflavin (Vitamin B2)	1.8 mg	90%
Niacin (as niacinamide)	15 mg	75%
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg	100%
Folate (as Folic acid USP 0.4 mg and L-methylfolate calcium 0.6 mg)	1 mg	125%
Vitamin B12 (as cobalamin)	5 mcg	63%
Iron (as polysaccharide iron complex)	29 mg	161%
Magnesium (as magnesium oxide)	25 mg	6%
Zinc (as zinc oxide)	15 mg	100%

**Other Ingredients:** Fructose, stearic acid, mono and diglycerides of edible fatty acids, croscarmellose sodium, natural berry flavor, modified food starch, maltodextrin, hydroxypropylmethylcellulose, silicon dioxide, citric acid, titanium dioxide (as color), polydextrose, magnesium stearate, malic acid, hydroxypropylcellulose, triacetin, corn starch, sucrose, acacia, polyethylene glycol, dibasic calcium phosphate, FD&C Blue #1 aluminum lake, FD&C Blue #2 aluminum lake, sodium ascorbate, medium chain triglycerides, dl-alpha-tocopherol, dl-alpha-tocopheryl.

**CONTRAINDICATIONS**

SELECT-OB® Chewable Caplets are contraindicated in patients with hypersensitivity to any of its components or color additives.

Folic acid is contraindicated in patients with untreated and uncomplicated pernicious anemia, and in those with anaphylactic sensitivity to folic acid.

Iron therapy is contraindicated in patients with hemochromatosis and patients with iron storage disease or the potential for iron storage disease due to chronic hemolytic anemia (e.g., inherited anomalies of hemoglobin structure or synthesis and/or red cell enzyme deficiencies, etc.), pyridoxine responsive anemia, or cirrhosis of the liver.

Cyanocobalamin is contraindicated in patients with sensitivity to cobalt or to cyanocobalamin (vitamin B12).

### **WARNING**

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

### **WARNINGS/PRECAUTIONS**

Vitamin D supplementation should be used with caution in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones. High doses of vitamin D can lead to elevated levels of calcium that reside in the blood and soft tissues. Bone pain, high blood pressure, formation of kidney stones, renal failure, and increased risk of heart disease can occur. Prolonged use of iron salts may produce iron storage disease.

Folic acid, especially in doses above 0.1 mg daily, may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestations remain progressive. The use of folic acid doses above 1 mg daily may precipitate or exacerbate the neurological damage of vitamin B12 deficiency.

Avoid overdosage. Keep out of the reach of children.

### **Drug Interactions**

High doses of folic acid may result in decreased serum levels of the anticonvulsant drugs; carbamazepine, fosphenytoin, phenytoin, phenobarbital, valproic acid. Folic acid may decrease a patient's response to methotrexate. Vitamin D supplementation should not be given with large amounts of calcium in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones. Zinc can inhibit the absorption of certain antibiotics; take at least 2 hours apart to minimize interactions. Consult appropriate references for additional specific vitamin-drug interactions.

### **Information for Patients**

Patients should be counseled to disclose all medical conditions, including use of all medications, vitamins and supplements, pregnancy, and breast-feeding.

### **ADVERSE REACTIONS**

Adverse reactions have been reported with specific vitamins and minerals, but generally at doses substantially higher than those in SELECT-OB<sup>®</sup> Chewable Caplets. However, allergic and idiosyncratic reactions are possible at any dose. Reported adverse events include skin ailments, gastrointestinal complaints, glucose abnormalities, and visual problems.

### **HOW SUPPLIED**

SELECT-OB<sup>®</sup> Chewable Caplets are available as a light blue, caplet debossed "EV0120". Available in bottle of 90 and as professional samples.

R<sub>x</sub>

## USAGE

SELECT-OB<sup>®</sup> Chewable Caplets provide vitamin and mineral supplementation prior to conception, throughout pregnancy, and during the postnatal period for the lactating and non-lactating mother.

## DIRECTIONS FOR USE

Before, during and after pregnancy, chew or swallow one blue SELECT-OB<sup>®</sup> Chewable Caplet daily, or as directed by a physician.

You should call your doctor for medical advice about serious adverse events. To report a serious adverse event or obtain product information, contact 1-877-324-9349.

## KEEP OUT OF REACH OF CHILDREN.

Store at room temperature, approximately 15°-30°C (59°-86°F), avoid excessive heat, light and moisture.

Manufactured for:

**EVERETT LABORATORIES, INC.**

**Chatham, NJ 07928**

**1-877-324-9349**

## PRINCIPAL DISPLAY PANEL - 90 Caplet Bottle Label

**0642-0120-90**

**Select-OB<sup>®</sup>**

Chewable Caplets  
Prenatal Supplement

**90 Caplets**

R<sub>x</sub>

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Vitamin B12 (as cobalamin)	5 mcg	83%
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Zinc (as zinc oxide)	15 mg	100%

Other Ingredients: Fructose, stearic acid, mono and diglycerides of edible fatty acids, croscarmellose sodium, natural berry flavor, modified food starch, maltodextrin, hydroxypropylmethylcellulose, silicon dioxide, citric acid, titanium dioxide (as color), polydextrose, magnesium stearate, malic acid, hydroxypropylcellulose, inulin, corn starch, sucrose, azela, polyethylene glycol, dibasic calcium phosphate, FD&C Blue #1 aluminum lake, FD&C Blue #2 aluminum lake, sodium ascorbate, medium chain triglycerides, dl-alpha-tocopherol, dl-alpha-tocopheryl.

Lot No.  
Exp. Date:

0642-0120-90

**Select-OB<sup>®</sup>**  
Chewable Caplets  
Prenatal Supplement

**90 Caplets**  
Rx

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**EVERETT LABORATORIES, INC.**  
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Select-OB<sup>®</sup> is a trademark of Everett Laboratories, Inc.  
U.S. Patent No. 7,560,123; 8,197,855  
Metofol<sup>®</sup> is a trademark of Merck KGaA, Darmstadt, Germany  
U.S. Patent No. 6,441,168B1; 5,997,915; 6,254,904; 6,808,725;  
7,172,778 and 7,674,490  
Rev. 02/14

**SELECT OB**

.beta.-carotene, vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, levomefolate calcium, cobalamin, iron, magnesium oxide, and zinc oxide tablet, chewable

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0642-0120
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>.BETA.-CAROTENE</b> (UNII: 01YAE03M7J) (.BETA.-CAROTENE - UNII:01YAE03M7J)	.BETA.-CAROTENE	600 [iU]
<b>VITAMIN A ACETATE</b> (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1100 [iU]
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	30 [iU]
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.6 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.8 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	15 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	2.5 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	0.4 mg
<b>LEVOMEFOLATE CALCIUM</b> (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	0.6 mg
<b>COBALAMIN</b> (UNII: 8406EY2OQA) (COBALAMIN - UNII:8406EY2OQA)	COBALAMIN	5 ug
<b>IRON</b> (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	29 mg
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	25 mg
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>FRUCTOSE</b> (UNII: 6YSS42VSEV)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>MALTO DEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALIC ACID</b> (UNII: 817L1N4CKP)	
<b>HYDROXYPROPYL CELLULOSE (TYPE H)</b> (UNII: RFW2ET671P)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>ACACIA</b> (UNII: 5C5403N26O)	

POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
SODIUM ASCORBATE (UNII: S033EH8359)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	

### Product Characteristics

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	EV0120
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0642-0120-90	90 in 1 BOTTLE		
2	NDC:0642-0120-03	3 in 1 BLISTER PACK		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		07/14/2014	

**Labeler** - Everett Laboratories, Inc. (071170534)

Revised: 7/2014

Everett Laboratories, Inc.