

**SELECT OB- .beta.-carotene, vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacin, pyridoxine hydrochloride, folic acid, levomefolate calcium, cobalamin, iron, magnesium, and zinc 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.

**SELECT-OB®
Prenatal Supplement**

Rx only

COMPOSITION

Each caplet contains:

Vitamin A	1,700 IU
Vitamin C	60 mg
Vitamin D	400 IU
Vitamin E	30 IU
Thiamine Mononitrate (Vitamin B ₁)	1.6 mg
Riboflavin (Vitamin B ₂)	1.8 mg
Niacin (as niacinamide)	15 mg
Vitamin B ₆ (as pyridoxine hydrochloride)	2.5 mg
Folic Acid	1 mg
Vitamin B ₁₂ (as Cyanocobalamin)	5 mcg
Elemental Iron (as polysaccharide iron complex)	29 mg
Magnesium (as magnesium oxide)	25 mg
Zinc (as zinc oxide)	15 mg

Other Ingredients: Fructose, Stearic Acid, Mono and Diglycerides, Croscarmellose Sodium, Mixed Berry Flavor WONF, Gelatin (Porcine), Silicon Dioxide, Citric Acid, Magnesium Stearate, Modified Food Starch, Hydroxypropylmethyl Cellulose, Malic Acid, Sucrose, Corn Starch, Dicalcium Phosphate, Sodium Ascorbate, Medium Chain Triglycerides, Sorbic Acid, Tocopherol Concentrate, Sodium Benzoate, dl-Alpha-Tocopherol, Butylated Hydroxytoluene (BHT), Tricalcium Phosphate. Coating: Hydroxypropylmethyl Cellulose, Titanium Dioxide, Polydextrose, Hydroxypropyl Cellulose, Triacetin, Polyethylene Glycol, FD&C Blue #1/Aluminum Lake, FD&C Blue #2/Aluminum Lake.
Contains Soy.

INDICATIONS AND USAGE

SELECT-OB® is indicated to provide vitamin, mineral supplementation prior to conception, throughout pregnancy, and during the postnatal period for the lactating and non-lactating mother.

CONTRAINDICATIONS

SELECT-OB® is 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 the reach of children. In case of accidental overdose, call a doctor or a Poison Control Center immediately.

WARNINGS/PRECAUTIONS

SELECT-OB[®] should be used with caution in patients with known sensitivity or allergy to soy.

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. Consumption of more than 3 grams of omega-3 fatty acids per day from all sources may lead to excessive bleeding.

Supplemental intake of omega-3 fatty acids such as DHA exceeding 2 grams per day is not recommended. 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. 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.

Pediatric Use

Not for pediatric use.

ADVERSE REACTIONS

Adverse reactions have been reported with specific vitamins and minerals, but generally at doses substantially higher than those in SELECT-OB[®].

DOSAGE AND ADMINISTRATION

Before, during and after pregnancy, one caplet daily, or as directed by a physician.

HOW SUPPLIED

SELECT-OB[®] is available as a light blue caplet debossed EV0077. Available in bottle of 90, (NDC 0642-0077-90).

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

Rx only

Manufactured for:

EVERETT LABORATORIES, INC.

Chatham, NJ 07928

1-877-324-9349

U.S. Patent No. 7,560,123 / 8,101,587 / 8,197,855

Select-OB[®] is a trademark of

Everett Laboratories, Inc.

Rev. 03/13

6876

PRINCIPAL DISPLAY PANEL - 90 Caplet Bottle Label

NDC 0642-0077-90

Select-OB[®]

Prenatal Supplement

90 Caplets

Rx only

Supplement Facts
Serving Size: 1 Caplet

Each caplet contains	Amount Per Serving	% Daily Value
	SELECT-OB	RDI Preg LG
Vitamin A	1,700 IU	21%
Vitamin C	60 mg	100%
Vitamin D	400 IU	100%
Vitamin E	30 IU	100%
Thiamine Mononitrate (Vitamin B ₁)	1.6 mg	94%
Riboflavin (Vitamin B ₂)	1.8 mg	90%
Niacin (as niacinamide)	15 mg	75%
Vitamin B ₆ (as pyridoxine hydrochloride)	2.5 mg	100%
Folic Acid	1 mg	125%
Vitamin B ₁₂ (as Cyanocobalamin)	5 mcg	63%
Elemental 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, Croscarmellose Sodium, Mixed Berry Flavor W/ONE, Gelatin (Porcine), Silicon Dioxide, Citric Acid, Magnesium Stearate, Modified Food Starch, Hydroxypropylmethyl Cellulose, Malic Acid, Sucrose, Corn Starch, Dicalcium Phosphate, Sodium Ascorbate, Medium Chain Triglycerides, Sorbic Acid, Tocopherol Concentrate, Sodium Benzoate, dl-Alpha-Tocopherol, Butylated Hydroxytoluene (BHT), Tricalcium Phosphate. Coating: Hydroxypropylmethyl Cellulose, Titanium Dioxide, Polydextrose, Hydroxypropyl Cellulose, Triacetin, Polyethylene Glycol, FD&C Blue #1/Aluminum Lake, FD&C Blue #2/Aluminum Lake. **Contains Soy.**

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Rx only
Manufactured for:
EVERETT LABORATORIES, INC., Chatham, NJ 07928
1-877-324-9349 U.S. Patent No. 7,560,123 / 8,101,587 / 8,197,855
Select-OB[®] is a trademark of Everett Laboratories, Inc. Rev. 03/13 6876

90 Caplets
Rx only

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SELECT OB

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0642-0077
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
.Beta.-Carotene (UNII: 01YAE03M7J) (.Beta.-Carotene - UNII:01YAE03M7J)	.Beta.-Carotene	600 [iU]
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1100 [iU]
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WP1EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	30 [iU]
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.6 mg
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	1.8 mg
Niacin (UNII: 2679MF687A) (Niacin - UNII:2679MF687A)	Niacin	15 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	2.5 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	0.4 mg
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	0.6 mg
Cobalamin (UNII: 8406EY2OQA) (Cobalamin - UNII:8406EY2OQA)	Cobalamin	5 ug
Iron (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7)	Iron	29 mg
Magnesium (UNII: I38ZP9992A) (Magnesium - UNII:I38ZP9992A)	Magnesium	25 mg
Zinc (UNII: J41CSQ7QDS) (Zinc - UNII:J41CSQ7QDS)	Zinc	15 mg

Inactive Ingredients

Ingredient Name	Strength
FRUCTOSE (UNII: 6YSS42VSEV)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALIC ACID (UNII: 817L1N4CKP)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
TRIACETIN (UNII: XHX3C3X673)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
ACACIA (UNII: 5C5403N26O)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
SODIUM ASCORBATE (UNII: S033EH8359)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)

.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)

Product Characteristics

Color	BLUE	Score	no score
Shape	OVAL	Size	19mm
Flavor	BERRY	Imprint Code	EV0077
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0642-0077-90	90 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		10/04/2005	

Labeler - Everett Laboratories, Inc. (071170534)

Revised: 9/2014

Everett Laboratories, Inc.