1-000-9296-00

### NDC 0642-0075-30 SELECT-OB®+DHA Prenatal Supplement with DHA Rx only

### COMPOSITION:

# Each SELECT-OB® caplet contains:

Vitamin A (as acetate & beta carotene)	1700 IU
Vitamin C (as ascorbic acid)	60 mg
Vitamin D3 (as cholecalciferol)	400IU
Vitamin E (as dl-alpha tocopheryl acetate)	30 IU
Thiamine mononitrate (Vitamin B1)	1.6 mg
Riboflavin (Vitamin B2)	1.8 mg
Niacin (as niacinamide)	15 mg
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg
Folic Acid	1 mg
Vitamin B12 (as cyanocobalamin)	5 mcg
Iron (as polysaccharide iron complex)	29 mg
Magnesium (as magnesium oxide)	25 mg
Zinc (as zinc oxide)	15 mg
Each DHA capsule provides: OMEGA-3 FATTY ACID:	
Docosahexaenoic Acid (DHA)	250 mg
Lauric Acid	20 mg

Other Ingredients: Fructose, Stearic Acid, Croscarmellose Sodium, Gelatin (bovine), Silicon Dioxide, Hydroxypropyl Cellulose, Magnesium Stearate, Hypromellose, Soy oil, Citric Acid, Maltodextrin, Titanium Dioxide, Polydextrose, Triacetin, Polyethylene Glycol, FD&C Blue No. 1 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake, Glycerin USP, Mixed berry flavor, orange flavor, water.

INDICATIONS AND USAGE: SELECT-OB®+DHA is indicated to provide vitamin, mineral, and omega-3 fatty acid supplementation prior to conception, throughout pregnancy, and during the postnatal period for the lactating and non-lactating mother, including individuals with known allergies to fish. SELECT-OB®+DHA does not contain fish, fish oils, fish proteins or fish byproducts.

CONTRAINDICATIONS: SELECT-OB®+DHA is contraindicated in patients with hypersensitivity to any of its components. Folic acid (pteroylglutamic 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®+DHA 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 B-12 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; carbamazepine, fosphenytoin, phenotorin, phenotori

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®+DHA. However, allergic and idiosyncratic reactions are possible at any dose. Reported adverse events include skin ailments, gastrointestinal complaints, glucose abnormalities, and visual problems.

DOSAGE AND ADMINISTRATION: Before, during and after pregnancy, chew or swallow one blue SELECT-OB® caplet and swallow one DHA gel

capsule daily, or as directed by a physician. **DESCRIPTION: 30 SELECT-OB® caplets and 30 DHA capsules** are co-packaged in child-resistant blister cards for prescription use. SELECT-OB® is a light blue caplet, imprint "EV0077". DHA is contained in an amber-colored gelatin capsule.

HOW SUPPLIED: Box of Unit-Dose pack of 30 (6 child resistant blister cards of 5 Select-OB® caplets and 5 DHA gel capsules each), (NDC 0642-0075-30).

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

### Rx only

U.S. Patent No. 7,560,123; 5,407,957; 5,492,938; 7,163,811 and other patents pending Select-OB® is a trademark of Everett Laboratories, Inc. (Rev. 09/11)

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