

# PNV-DHA Label

## Rx Only Dietary Supplement

**DESCRIPTION:** PNV-DHA is a prescription prenatal/postnatal multivitamin/mineral/essential fatty acid softgel. Each softgel is cobalt blue in color, opaque, and imprinted with “BP321” on one side and blank on the other. PNV-DHA can also be beneficial in improving the nutritional status of women prior to conception.

Supplement Facts			
Serving Size: 1 Softgel Servings Per Container:30			
	Amount Per Serving	% Daily Value	% Daily Value for Pregnant and Lactating Women
Calories	10		
Total Fat	0.5 g	<1%*	<1%*
Vitamin C (ascorbic acid)	85 mg	94%	71%
Vitamin D (cholecalciferol)	5 mcg	25%	33%
Vitamin E (dl-alpha tocopheryl acetate)	4.5 mg	30%	24%
Vitamin B <sub>6</sub> (pyridoxine HCl)	25 mg	1471%	1250%
Folate ((6S)-N5-methyl-tetrahydrofolic acid calcium salt (equivalent to 600 mcg of folic acid) and folic acid, USP 400 mcg)	1700 mcg DFE	425%	283%
Vitamin B <sub>12</sub> (cyanocobalamin)	12 mcg	500%	429%
Calcium (calcium carbonate)	140 mg	11%	11%
Iron (ferrous fumarate)	27 mg	150%	100%
Magnesium (magnesium oxide)	45 mg	11%	12%
Docosahexaenoic Acid (DHA from omega-3 fatty acids)	300 mg	†	†
† Daily Value (DV) not established. *Percent Daily Values (DV) are based on a 2,000 calorie diet			

**PNV-DHA contains fish oil and soy.**

**OTHER INGREDIENTS:** Beeswax, soy lecithin and vegetable shortening. Coating contains: Bovine gelatin, FD&C Blue No. 1, FD&C Red No. 3, glycerin, purified water and titanium dioxide. Contains Soy.

**INDICATIONS:** PNV-DHA is a multivitamin/multimineral fatty acid dietary supplement indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and nonlactating mothers.

**CONTRAINDICATIONS:** PNV-DHA is contraindicated in patients with a known hypersensitivity to any of the ingredients.

**WARNINGS:** Ingestion of more than 3 grams of omega-3 fatty acids (such as DHA) per day has been shown to have potential antithrombotic effects, including an increased bleeding time and International Normalized Ration (INR). Administration of omega-3 fatty acids should be avoided in patients taking anticoagulants and in those known to have an inherited or acquired predisposition to bleeding.

**PRECAUTIONS:** Folic acid alone is improper therapy in the treatment of pernicious anemia and other

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megaloblastic anemias where Vitamin B<sub>12</sub> is deficient. Folic acid in doses above 1.0 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

**DIRECTIONS:** Adults only. Take one capsule daily, as a dietary supplement, or as directed by a physician.

**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 poison control center immediately.

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

**DOSAGE AND ADMINISTRATION:** Before, during and/or after pregnancy, one softgel daily or as directed by a physician.

**HOW SUPPLIED:** Bottles of 30 softgels (42192-321-30). The listed product number is not a National Drug Code. Instead, Acella Pharmaceuticals has assigned a product code formatted according to standard industry practice to meet the formatting requirements of pharmacy and healthcare insurance computer systems.

**STORAGE:** Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature.]

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **Note: This is not an Orange Book product. No representation is made as to generic status or bioequivalency.**

**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.**

**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

**MANUFACTURED FOR:**

Acella Pharmaceuticals, LLC

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