PNV-OMEGA Label

Rx Only

DESCRIPTION: PNV - Omega is a prescription prenatal/postnatal dietary supplement softgel capsule that contains multivitamins and minerals along with essential fatty acids. Each softgel is green in color, opaque and imprinted with "332" on one side.

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 (as ascorbic acid)	85 mg	94%	71%
Vitamin D (as cholecalciferol)	5 mcg	25%	33%
Vitamin E (as d-alpha tocopherol)	6.7 mg	45%	35%
Vitamin B6 (as pyridoxine HCl)	25 mg	1471%	1250%
Folate (as (6S)-N5-methyl-tetrahydrofolic acid calcium salt (equivalent to 600 mcg of folic acid) and folic acid, USP 400 mcg) (No more than 10% D-Isomer)	1700 mcg DFE	425%	283%
Vitamin B12 (as cyanocobalamin)	12 mcg	500%	429%
Biotin	250 mcg	833%	714%
Calcium (as calcium carbonate)	140 mg	11%	11%
Iron (as ferrous fumarate)	28 mg	156%	104%
Iodine (as potassium iodide)	150 mcg	100%	52%
Magnesium (as magnesium oxide)	45 mg	11%	11%
Docosahexaenoic Acid (DHA)	300 mg	†	†
Eicosapentaenoic Acid (EPA) (from 340 mg omega-3 fatty acids from fish oil)	40 mg	†	†

† Daily Value (DV) not established.
*Percent Daily Values (DV) are based on a 2,000 calorie diet

OTHER INGREDIENTS: Soy lecithin, vegetable shortening, and yellow beeswax. Gelatin capsule (bovine gelatin, FD&C Blue #1, FD&C Yellow #5, FD&C Yellow #6, glycerin, purified water and titanium dioxide. **Contains soy. Contains FD&C Yellow No. 5 (tartrazine) and FD&C Yellow No. 6.**

PNV - Omega is a multivitamin/multimineral dietary supplement for use in the dietary management of patients with nutritional deficiencies or are in need of nutritional supplementation.

CONTRAINDICATIONS: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

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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 Ratio (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.

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.

PRECAUTIONS: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B12 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.
Biotin levels higher than the recommended daily allowance may cause interference with some laboratory tests, including cardiovascular diagnostic test (e.g. troponin) and hormone tests, and may lead to incorrect test results. Tell your healthcare provider about all prescription and over-the-counter medicines, vitamins, and dietary supplements that you take, including biotin.
This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

DRUG INTERACTIONS: PNV-Omega is not recommended for and should not be given to patients receiving levodopa because the action of levodopa is antagonized by pyridoxine. There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g., Aspirin, Heparin, Clopidogrel).

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: PNV - Omega is supplied in child-resistant bottles of 30 softgels (42192-332-30). The listed product is not a National Drug Code, but has merely been formatted to comply with standard industry practice for pharmacy and insurance computer systems.

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

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

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All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **Please note: This is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency.** Each person recommending a prescription substitution using this product shall make such recommendations based on each such person's professional opinion and knowledge, upon evaluating the dietary ingredients, other ingredients and information provided herein.

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.

MANUFACTURED FOR:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30005
1-800-541-4802
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