

**PNV-OMEGA- ascorbic acid, cholecalciferol, .alpha.-tocopherol, pyridoxine, folic acid, cyanocobalamin, calcium carbonate, ferrous fumarate, potassium iodide, magnesium, doconexent, icosapent capsule, gelatin coated
Acella Pharmaceuticals, LLC**

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.

PNV - Omega

PNV - Omega

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

	Amount per serving	% Daily Value
Vitamin C (as ascorbic acid)	85 mg	142%
Vitamin D3 (as cholecalciferol)	200 IU	50%
Vitamin E (as d-alpha-tocopherol)	10 IU	33%
Vitamin B6 (as pyridoxine HCl)	25 mg	1250%
Folate (as ((6S)-N5-methyltetrahydrofolic acid calcium salt (equivalent to 600 mcg of folic acid) and folic acid, USP 400 mcg) (No more than 10% D-Isomer)	1 mg	250%
Vitamin B12 (as cyanocobalamin)	12 mcg	200%
Biotin	250 mcg	83%
Calcium (calcium carbonate)	140 mg	14%
Iron (as ferrous fumarate)	28 mg	156%
Iodine (as potassium iodide)	150 mcg	100%
Magnesium (as magnesium oxide)	45 mg	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.

OTHER INGREDIENTS

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

INDICATIONS

PNV - Omega is a multivitamin/ multimineral dietary supplement indicated 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.

WARNING

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.

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.

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

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

Rev 1218-04

PRINCIPAL DISPLAY PANEL - 30 Softgel Tablets

NDC 42192-332-30

PNV - Omega

Rx Prenatal Vitamin and DHA

Rx Only

30 Softgels

Acella PHARMACEUTICALS, LLC

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

42192-332-30

PNV - Omega

Rx Prenatal Vitamin and DHA

Rx Only

30 Softgels

DOSAGE: One softgel daily or as directed by a physician. See package insert for full prescribing information.

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.

KEEP THIS PRODUCT OUT OF REACH OF CHILDREN

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. See package insert for more details.

MANUFACTURED FOR:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30005
1-800-541-4802 Rev 1218-03 3 42192-33230 0

SUPPLEMENT FACTS	Amount per serving	% Daily Value
Serving Size: 1 softgel		
Vitamin C (as ascorbic acid)	85 mg	142%
Vitamin D3 (as cholecalciferol)	200 IU	50%
Vitamin E (as α -tocopherol)	10 IU	33%
Vitamin B6 (as pyridoxine HCl)	25 mg	1250%
Folate (as (6S)-5-methyltetrahydrofolic acid calcium salt, equivalent to 600 mcg of folic acid and folic acid, USP 400 mcg) (No more than 10% D-Isomer)	12 mcg	200%
Vitamin B12 (as cyanocobalamin)	250 mcg	83%
Biotin	140 mcg	14%
Calcium (calcium carbonate)	28 mg	156%
Iron (as ferrous fumarate)	150 mcg	100%
Iodine (as potassium iodide)	45 mcg	11%
Magnesium (as magnesium oxide)	300 mg	†
Docosahexaenoic Acid (DHA)	40 mg	†
Eicosapentaenoic Acid (EPA)	from 340 mg omega-3 fatty acids from fish oil	†

† Daily Value (DV) not established.

PNV-OMEGA

ascorbic acid, cholecalciferol, .alpha.-tocopherol, pyridoxine, folic acid, cyanocobalamin, calcium carbonate, ferrous fumarate, potassium iodide, magnesium, doconexent, icosapent capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42192-332
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	85 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	200 [iU]
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL	10 [iU]
PYRIDOXINE (UNII: KV2JZ1BI6Z) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	250 ug
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	140 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	28 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	150 ug
MAGNESIUM OXIDE (UNII: 3A3U0G171G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	45 mg
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	300 mg
ICOSAPENT (UNII: AAN7QOV9EA) (ICOSAPENT - UNII:AAN7QOV9EA)	ICOSAPENT	40 mg

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
CORN OIL (UNII: 8470G57WFM)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	

Product Characteristics

Color	green	Score	no score
Shape	CAPSULE	Size	25mm
Flavor		Imprint Code	332
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-332-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/19/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/19/2010	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-332)

Revised: 1/2024

Acella Pharmaceuticals, LLC