

**PNV-DHA- ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, pyridoxine, folic acid, cyanocobalamin, calcium, ferrous fumarate, magnesium, doconexent 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-DHA

Rx Only

DESCRIPTION: PNV-DHA is a prescription prenatal/postnatal multivitamin/mineral/essential fatty acid softgel. Each softgel is blue in color, opaque and imprinted with “BP 321” on one side.

Supplement Facts			
Serving Size 1 Tablet			
Amount Per Serving		% DV	%DV for Pregnant or Lactating Women
Vitamin C	85 mg	142%	142%
Vitamin D ₃	200 IU	50%	50%
Vitamin E	10 IU	33%	33%
Vitamin D ₆	25 mg	1250%	1000%
Folate	1 mg	250%	125%
(L-methylfolate calcium 676 mcg (as Xolafin-B™ *) molar equivalent to 600 mcg of Folic Acid)			
(folic acid, USP 400 mcg)			
Vitamin B ₁₂	12 mcg	200%	150%
Calcium	140 mg	14%	11%
Iron (ferrous fumarate)	27 mg	150%	150%
Magnesium	45 mg	11%	10%
Docosahexaenoic Acid (DHA) (from omega-3 fatty acids)	300 mg	†	†

* Percent Daily Values are based on a 2000 calorie diet

† Daily Value (DV) not established

OTHER INGREDIENTS: bee’s wax, hydrogenated vegetable oil, lecithin, gelatin, glycerin, purified water, titanium dioxide, FD&C Blue #1, FD&C Red #3.

INDICATIONS: PNV-DHA is a multivitamin/multimineral nutritional 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-DHA is supplied in child-resistant bottles of 30 softgels (NDC# 42192-321-30).

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.

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 active ingredients, excipients, inactive ingredients and chemical information provided herein.

MANUFACTURED FOR: Acella Pharmaceuticals, LLC

9005 Westside Parkway

Alpharetta, GA 30009

1-800-541-4802

Rev. 04/10v6

**Xolafin-B™ is a trademark of Acella Pharmaceuticals, LLC*

PRINCIPAL DISPLAY PANEL - 30 Softgel Tablets

NDC 42192-321-30

PNV-DHA

Rx Prenatal Vitamin and DHA

Rx Only 30 Softgels

**Acella
PHARMACEUTICALS, LLC**

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Serving Size 1 Tablet			
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(folic acid, USP 400 mcg)			
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NDC 42192-321-30

PNV-DHA

Rx Prenatal Vitamin and DHA

Rx Only

30 Softgels

Acella
PHARMACEUTICALS, LLC

OTHER INGREDIENTS: bees wax, hydrogenated vegetable oil, lecithin, gelatin, glycerin, purified water, titanium dioxide, FD&C Blue #1, FD&C Red #3. Sugar, lactose, yeast and gluten free.

DOSEAGE: 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 OUT OF 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. 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 30009
1-800-541-4802
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Lot Number/Exp. Date:



Rev: 0410v7

PNV-DHA

ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, pyridoxine, folic acid, cyanocobalamin, calcium, ferrous fumarate, magnesium, doconexent capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42192-321
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 [iU]
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	200 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	10 [iU]
PYRIDOXINE (UNII: KV2JZ1BI6Z) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	25 [iU]
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
CALCIUM (UNII: SY7Q814VUP) (CALCIUM - UNII:SY7Q814VUP)	CALCIUM	140 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg
MAGNESIUM (UNII: I38ZP9992A) (MAGNESIUM - UNII:I38ZP9992A)	MAGNESIUM	45 mg
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	300 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
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	blue	Score	no score
Shape	CAPSULE	Size	25mm
Flavor		Imprint Code	BP;321
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-321-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/02/2009	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-321)

Revised: 1/2024

Acella Pharmaceuticals, LLC