

**PNV-SELECT- vitamin a acetate, ascorbic acid, cholecalciferol, alpha-tocopherol acetate, dl, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, biotin, calcium pantothenate, calcium carbonate, ferrous fumarate, potassium iodide, magnesium oxide, zinc oxide and cupric oxide tablet, film 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-Select

Rx Only

DESCRIPTION: PNV-Select is a prescription prenatal dietary supplement tablet that contains multivitamins and minerals, which are delivered in the form of a white, oval, oil- and water-soluble, film-coated tablet debossed with “320” on one side.

SUPPLEMENT FACTS

Serving Size: 1 tablet

	Amount per serving	% Daily Value
Vitamin A (as beta carotene)	2,500 IU	50%
Vitamin C (as ascorbic acid)	80 mg	133%
Vitamin D3 (as cholecalciferol)	400 IU	100%
Vitamin E (as dl-alpha-tocopherol acetate)	10 IU	33%
Vitamin B1 (as thiamine mononitrate)	3 mg	200%
Vitamin B2 (as Riboflavin)	3.4 mg	200%
Niacinamide USP	20 mg	100%
Vitamin B6 (as pyridoxine HCl)	20 mg	1000%
Folate (as ((6S)-N5-Methyltetrahydrofolic acid calcium salt equivalent to 600 mcg of folic acid) and 400 mcg of folic acid, USP)	1 mg	250%
Vitamin B12 (as cyanocobalamin) USP	12 mcg	200%
Biotin	300 mcg	100%
Pantothenic Acid (as calcium-D pantothenate)	6 mg	60%
Calcium (as calcium carbonate)	120 mg	12%
Iron (as ferrous fumarate) USP	27 mg	150%
Iodine (as potassium iodide)	150 mcg	100%
Magnesium (as magnesium oxide) USP	30 mg	8%
Zinc (as zinc oxide) USP	15 mg	100%
Copper (as cupric oxide)	2 mg	100%

OTHER INGREDIENTS: Dicalcium Phosphate, Cellulose, Croscarmellose Sodium, Stearic Acid, Silicon Dioxide, Magnesium Stearate, Film Coating (Hydroxy Propyl Methyl Cellulose, Triacetin, Titanium Dioxide).

INDICATIONS: PNV-Select 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: 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 AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

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: One tablet daily or as directed by a physician.

HOW SUPPLIED: PNV-Select is supplied in child-resistant bottles of 90 tablets (42192-320-90). 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.]

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 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 0719-03

PRINCIPAL DISPLAY PANEL - Film Coated Tablets

NDC 42192-320-90

PNV-Select

Prenatal Multivitamin

Dietary Supplement

Film Coated Tablets

Rx Only 90 Tablets

Acella

PHARMACEUTICALS, LLC

42192-320-90

PNV-SelectPrenatal Multivitamin
Dietary Supplement
Film Coated Tablets

Rx Only

90 Tablets

**SUPPLEMENT FACTS**

Serving Size: 1 tablet	Amount per serving	% Daily Value
Vitamin A (as retinyl acetate)	2,500 IU	50%
Vitamin C (as ascorbic acid)	80 mg	133%
Vitamin D3 (as cholecalciferol)	400 IU	100%
Vitamin E (as d-alpha-tocopherol acetate)	10 IU	20%
Vitamin B1 (as thiamine mononitrate)	3 mg	200%
Riboflavin (Vitamin B2)	3.4 mg	200%
Niacinamide (Vitamin B3)	20 mg	100%
Vitamin B6 (pyridoxine HCl)	2 mg	100%
Folate (as 5-MTHF USP)	1 mg	200%
Biotin (Vitamin B7)	300 mcg	100%
Acid Calcium Salt	12 mg	100%
Vitamin B12 (as cyanocobalamin) USP	300 mcg	100%
Biotin	300 mcg	100%
Pantothenic Acid (as calcium-D-pantothenate)	6 mg	60%
Calcium (as calcium carbonate)	120 mg	12%
Iron (as ferrous fumarate) USP	27 mg	15%
Iodine (as potassium iodide)	150 mcg	100%
Magnesium (as magnesium oxide) USP	30 mg	6%
Zinc (as zinc oxide) USP	15 mg	100%
Cupric (as cupric oxide)	2 mg	100%

OTHER INGREDIENTS: Dicalcium Phosphate, Cellulose, Croscarmellose Sodium, Stearic Acid, Silicon Dioxide, Magnesium Stearate, Film Coating (Hydroxy Propyl Methyl Cellulose, Triacetin, Titanium Dioxide).

DOSAGE: One tablet 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 30022
1-800-541-4622 Rev 07/16-01

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PNV-SELECT

vitamin a acetate, ascorbic acid, cholecalciferol, alpha-tocopherol acetate, dl, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, biotin, calcium pantothenate, calcium carbonate, ferrous fumarate, potassium iodide, magnesium oxide, zinc oxide and cupric oxide tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42192-320
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	2500 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	80 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	10 [iU]
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.4 mg
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	20 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
BIOTIN (UNII: 6S06U10H04) (BIOTIN - UNII:6S06U10H04)	BIOTIN	300 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	6 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	120 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	150 ug
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	30 ug
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	15 ug
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	2 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	320
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-320-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/04/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/01/1990	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Registrant - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-320)