

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

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**PNV-DHA + DOCUSATE**

**Rx Only**

**DESCRIPTION**

PNV-DHA + Docusate is a prescription prenatal/postnatal multivitamin/multimineral softgel with DHA. Each softgel is red in color and imprinted with “323” on one side.

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**SUPPLEMENT FACTS**

**Serving Size: 1 softgel**

	<b>Amount Per Serving</b>	<b>% Daily Value</b>
Vitamin C (as ascorbic acid, USP)	28 mg	47%
Calcium (tribasic calcium phosphate, NF)	160 mg	16%
Iron (as ferrous fumarate, USP)	27 mg	150%
Vitamin D <sub>3</sub> (as cholecalciferol, USP)	400 IU	100%
Vitamin E (as d-alpha-tocopherol acetate, USP)	30 IU	100%
Vitamin B <sub>6</sub> (as pyridoxine HCl, USP)	25 mg	1250%
Folic Acid, USP	1.25 mg	313%
DHA (docosahexaenoic acid)	300 mg	†
Docusate sodium, USP	55 mg	†

† Daily Value (DV) not established.

**OTHER INGREDIENTS**

Bovine Gelatin, Glycerin, Soybean Oil, Soy Lecithin, Purified Water, Yellow Beeswax,

FD&C Red # 40, Titanium Dioxide, Orange Cream Flavor, Ethyl Vanillin, FD&C Yellow # 6, and FD&C Blue #1. Contains soy.

## **INDICATIONS**

PNV-DHA + Docusate is a multivitamin/mineral prescription dietary supplement indicated for use in improving the nutritional status of women prior to conception, throughout pregnancy, and in the postnatal period for both lactating and nonlactating mothers.

## **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 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.

## **ADVERSE REACTIONS**

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

**CAUTION:**Exercise caution to ensure that the prescribed dosage of DHA does not exceed 1 grams (1000 mg) daily.

## **DOSAGE AND ADMINISTRATION**

Usual adult dose is one (1) softgel daily or as directed by a physician.

**KEEP OUT OF REACH OF CHILDREN.**

## **HOW SUPPLIED**

PNV-DHA + Docusate is supplied in child-resistant bottles of 30 softgels (42192-323-30). The listed product number 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"]. Protect from light and heat.

## **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 30022  
1-800-541-4802  
Rev. 0717-01

## **PRINCIPAL DISPLAY PANEL - 30 Softgel Tablets**

42192-323-30

### **PNV-DHA+Docusate**

R<sub>x</sub> Prenatal Vitamin and DHA  
Dietary Supplement

**R<sub>x</sub> Only            30 Softgels**

**Acella  
PHARMACEUTICALS, LLC**

3  
42192-32330  
8

### SUPPLEMENT FACTS

Serving Size: 1 softgel

	Amount per serving	% Daily Value
Vitamin C (as ascorbic acid, USP)	28 mg	47%
Calcium (tribasic calcium phosphate, NF)	160 mg	16%
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Vitamin D3 (as cholecalciferol, USP)	400 IU	100%
Vitamin E (as d-alpha-tocopherol acetate, USP)	30 IU	100%
Vitamin B6 (as pyridoxine HCl, USP)	25 mg	1250%
Folic Acid, USP	1.25 mg	313%
DHA (docosahexaenoic acid)	300 mg	†
Docosate sodium, USP	55 mg	†

† Daily Value (DV) not established.

**OTHER INGREDIENTS:** Bovine Gelatin, Glycerin, Soybean Oil, Soy Lecithin, Purified Water, Yellow Beeswax, FD&C Red # 40, Titanium Dioxide, Orange Cream Flavor, Ethyl Vanillin, FD&C Yellow # 6, and FD&C Blue #1.  
Contains soy.

42192-323-30

## PNV-DHA + Docosate

Rx Prenatal Vitamin  
and DHA  
Dietary Supplement

Rx only

30 Softgels



**DOSAGE AND ADMINISTRATION:** Usual adult dose is one (1) softgel daily or as directed by a physician. See inside 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.**

Store at 15° - 30°C (59° - 86°F) [See USP].

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. No representation is made as to generic status or bioequivalency.** See inside for more details.

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Acella Pharmaceuticals, LLC  
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1-800-541-4802 Rev. 0717-01

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PEEL HERE

## PNV-DHA

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

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:42192-323
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	28 mg
<b>CALCIUM</b> (UNII: SY7Q814VUP) (CALCIUM - UNII:SY7Q814VUP)	CALCIUM	160 mg
<b>FERROUS FUMARATE</b> (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	30 [iU]
<b>PYRIDOXINE</b> (UNII: KV2JZ1BI6Z) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	25 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1.25 mg
<b>DOCONEXENT</b> (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	300 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>GELATIN TYPE B BOVINE (230 BLOOM)</b> (UNII: WL1404U79)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>ORANGE</b> (UNII: 5EVU04N5QU)	
<b>ETHYL VANILLIN</b> (UNII: YC9ST449YJ)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	25mm
<b>Flavor</b>		<b>Imprint Code</b>	323
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-323-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2010	03/31/2027

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/01/2010	03/31/2027

**Labeler** - Acella Pharmaceuticals, LLC (825380939)

### Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-323)

Revised: 3/2026

Acella Pharmaceuticals, LLC