**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.

**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% |
| Iron (as ferrous fumarate, USP) | 27 mg | 150% |
| Vitamin $D_3$ (as cholecalciferol, USP) | 400 IU | 100% |
| Vitamin E (as d-alpha-tocopherol acetate, USP) | 30 IU | 100% |
| Vitamin $B_6$ (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 $B_{12}$ 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**

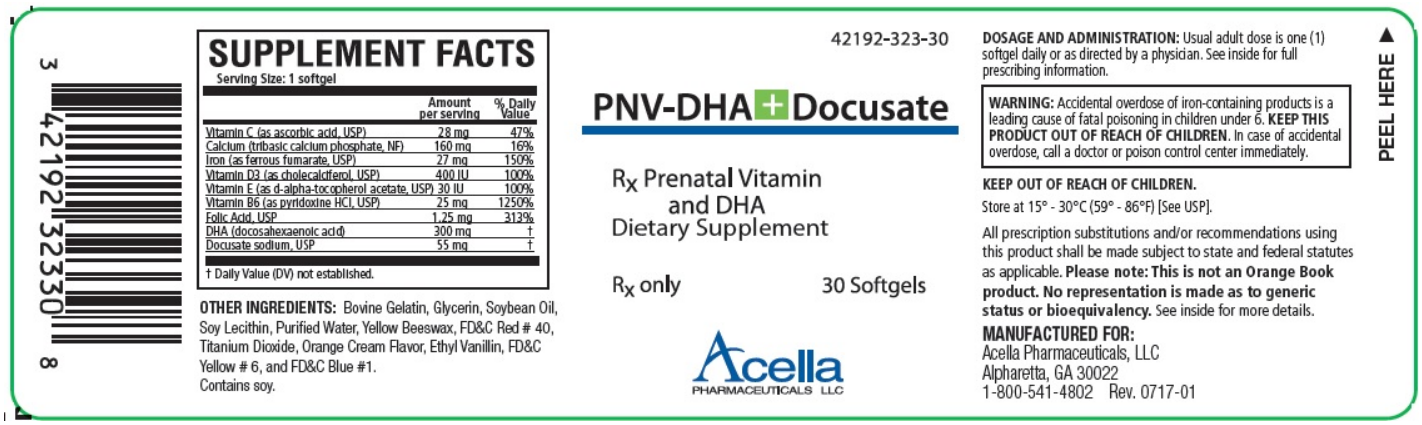
42192-323-30

**PNV-DHA+Docusate**

$R_x$ Prenatal Vitamin and DHA
Dietary Supplement

**$R_x$ Only 30 Softgels**

**Acella**
**PHARMACEUTICALS, LLC**




# PNV-DHA

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

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:42192-323 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

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

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | RED | **Score** | no score |
| **Shape** | CAPSULE | **Size** | 25mm |
| **Flavor** | | **Imprint Code** | 323 |
| **Contains** | | | |

**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 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 10/01/2010 | |

## Labeler - Acella Pharmaceuticals, LLC (825380939)

## Establishment

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

Revised: 1/2024 Acella Pharmaceuticals, LLC