

**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.**