

**VIRT-PN DHA- ascorbic acid, cholecalciferol, .alpha.-tocopherol, d-, pyridoxine hydrochloride, levomefolate calcium, folic acid, cyanocobalamin, calcium carbonate, ferrous fumarate, magnesium oxide, and doconexent capsule**  
**Virtus Pharmaceuticals**

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**Virt-PN DHA**  
**PRENATAL/POSTNATAL**

<b>Supplement Facts</b> <b>Serving Size: 1 Softgel</b>	<b>Amount Per Serving</b>	<b>% Daily Value for Pregnant and Lactating Women</b>
<b>Vitamin C</b> (ascorbic acid)	85 mg	142%
<b>Vitamin D</b> (Vitamin D3 as cholecalciferol)	200 IU	50%
<b>Vitamin E</b> (d-alpha tocopherol)	10 IU	33%
<b>Vitamin B<sub>6</sub></b> (pyridoxine HCl)	25 mg	1000%
<b>Folate</b> (L-Methylfolate calcium, or 6(S)-5-MTHF-Ca 600 mcg) (folic acid, USP 400 mcg)	1 mg	125%
<b>Vitamin B<sub>12</sub></b> (cyanocobalamin)	12 mcg	150%
<b>Calcium</b> (calcium carbonate)	140 mg	11%
<b>Iron</b> (ferrous fumarate)	27 mg	150%
<b>Magnesium</b> (magnesium oxide)	45 mg	10%
<b>Docosahexaenoic Acid (DHA)</b>	300 mg*	†

\* From at least 330 mg purified fish oil.

† Daily Value not established

Other Ingredients: Soybean Oil, Gelatin, Glycerin, DI Water, Yellow Beeswax, Lecithin, Annatto Extract, Titanium Dioxide, FD&C Red #40, and FD&C Blue #1.

**CAUTION: Contains Soy, Fish Oil, FD&C Red #40, and FD&C Blue #1.**

## **DESCRIPTION**

Virt-PN DHA is a prescription prenatal/postnatal multivitamin/mineral dietary supplement with fish-based DHA and should be administered under the supervision of a licensed medical practitioner.

## **DOSAGE AND ADMINISTRATION**

Before, during and/or after pregnancy, one softgel daily or as directed by a licensed healthcare practitioner regardless of lactation status.

## **CAUTION**

Ingestion of more than 3 grams per day of omega-3 fatty acids (ALA, EPA, and DHA) may have potential antithrombotic activities, or effects, and may increase bleeding times. Administration of omega-3 fatty acids, including DHA, should be avoided in patients with inherited or acquired bleeding diathesis, including those taking anticoagulants. Exercise caution to ensure that the prescribed dosage of DHA does not exceed 1 gram (1000 mg) per day.

**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.**

## **CAUTION**

High levels of folic acid may, especially in older adults, hide signs of Vitamin B-12 deficiency (such as pernicious anemia), a condition that can cause nerve damage.

Store at 20° to 25°C (68° to 77°F). Excursions permitted to 15° to 30°C (59° to 86°F). Protect from light and moisture. Dispense in a tight, light-resistant container. Notice: Contact with moisture may produce surface discoloration or erosion.

**Call your licensed medical practitioner about side effects. You may report side effects by calling Virtus at 1-888-848-3593 or FDA at 1-800-FDA-1088.**

## **HOW SUPPLIED**

Supplied as oblong, annatto-colored softgel, imprinted "340" and dispensed in 30 count bottles.

Manufactured for:

Virtus Pharmaceuticals, LLC

Tampa, Florida 33619 1-888-848-3593

Rev. 12/2015

## **PRINCIPAL DISPLAY PANEL - 30 Softgel Bottle Label**

**VIRTUS**

PHARMACEUTICALS

69543-340-30

**Virt-PN DHA**

**PRENATAL/POSTNATAL**

**Prescription Multivitamin/Mineral**

**Dietary Supplement with Fish-Based DHA**

**R<sub>x</sub>**

**30 Softgels**

Made in USA



69543-340-30

# Virt-PN DHA

PRENATAL/POSTNATAL

Prescription Multivitamin/Mineral  
Dietary Supplement with Fish-Based DHA

Rx  
30 Softgels

Made In USA

## Supplement Facts

Amount Per Serving	% Daily Value for Pregnant & Lactating Women
Vitamin C (Ascorbic acid)	85 mg 142%
Vitamin D (Vitamin D <sub>3</sub> as cholecalciferol)	200 IU 50%
Vitamin E (d-alpha tocopherol)	10 IU 33%
Vitamin B <sub>6</sub> (Pyridoxine HCl)	25 mg 1000%
Folate (L-Methylfolate calcium, or 6(S)-5-MTHF-Ca 600 mcg) (folic acid USP 400 mcg)	1 mg 125%
Vitamin B <sub>12</sub> (or cyanocobalamin)	12 mcg 150%
Calcium (calcium carbonate)	140 mg 11%
Iron (ferrous fumarate)	27 mg 150%
Magnesium (magnesium oxide)	45 mg 10%
Docosahexaenoic Acid (DHA)	300 mg* †

\*Daily Value not established. †From at least 300 mg purified fish oil.

Other Ingredients: Soybean Oil, Gelatin, Glycerin, D1 Water, Yellow Beeswax, Lecithin, Anatto Extract, Titanium Dioxide, FD&C Yellow #6, and FD&C Blue #1.

**CAUTION:** Contains Soy, Fish Oil, FD&C Red #40, and FD&C Blue #1.  
**DESCRIPTION:** Virt-PN DHA is a prescription prenatal/postnatal multivitamin/mineral dietary supplement with fish-based DHA, and should be administered under the supervision of a licensed medical practitioner.

**DOSE AND ADMINISTRATION:** Before, during and/or after pregnancy, one softgel daily or as directed by a licensed healthcare practitioner regardless of trimester status.  
**CAUTION:** Ingestion of more than 3 grams per day of omega-3 fatty acids (ALA, EPA, and DHA) may have potential anti-thrombotic activities, or effects, and may increase bleeding times. Administration of omega-3 fatty acids, including DHA, should be avoided in patients with inherited or acquired bleeding diatheses, including those taking anticoagulants. Exercise caution to ensure that the prescribed dosage of DHA does not exceed 1 gram (1000 mg) per day.

**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.

**CAUTION:** High levels of folic acid may, especially in older adults, hide signs of Vitamin B-12 deficiency (such as pernicious anemia), a condition that can cause nerve damage.  
**STORAGE:** Store at 20° to 25° (68° to 77°F). Excursions permitted to 15° to 30° (59° to 86°F). Protect from light and moisture. Dispense in a tight, light-resistant container.

Call your licensed medical practitioner about side effects. You may report side effects by calling Virtus at 1-888-846-3593 or FDA at 1-800-FDA-1088.

**HOW SUPPLIED:** Supplied as oblong, amber-colored softgel, imprinted "340" and dispensed in 30 count bottles.

Manufactured for:  
Virtus Pharmaceuticals, LLC  
Tampa, FL 33619  
1-888-846-3593  
Rev. 12/2015



3 69543 34030 2

Lot:  
Exp:

## VIRT-PN DHA

ascorbic acid, cholecalciferol, .alpha.-tocopherol, d-, pyridoxine hydrochloride, levomefolate calcium, folic acid, cyanocobalamin, calcium carbonate, ferrous fumarate, magnesium oxide, and doconexent capsule

### Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69543-340
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 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	200 [iU]
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL, D-	10 [iU]
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE	25 mg
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	600 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	400 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	140 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW895810WR)	FERROUS CATION	27 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	45 mg
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	300 mg

### Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 22A36H0S2V)	
SOYBEAN OIL (UNII: 241ATL177A)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)				
ANNATTO (UNII: 6PQP1V1B6O)				
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69543-340-30	30 in 1 BOTTLE		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
DIETARY SUPPLEMENT		09/08/2015		

<b>Supplement Facts</b>		
Serving Size :	Serving per Container :	
	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	25 mm	
imprint		

**Labeler** - Virtus Pharmaceuticals (079659493)