VIRT-NATE DHA- ascorbic acid, cholecalciferol, .alpha.-tocopherol, d-, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, folic acid, cyanocobalamin, ferrous fumarate, magnesium oxide, zinc oxide, cupric sulfate, and omega-3 fatty acids capsule
Virtus Pharmaceuticals

Virt-Nate DHA

Prenatal/Postnatal Prescription Dietary Supplement

69543-**370**-30

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DESCRIPTION

Virt-Nate DHA is an orally administered prenatal/postnatal prescription dietary supplement with DHA and should be administered under the supervision of a licensed medical practitioner.

DIRECTIONS FOR USE

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

Supplement Facts **Serving Size: 1 Softgel**		
	Amount Per Serving	**% Daily Value for Pregnant & Lactating Women**
Vitamin C (as ascorbic acid)	100 mg	167%
Vitamin D (Vitamin D_3 as cholecalciferol)	400 IU	100%
Vitamin E (as d-alpha tocopherol)	30 IU	100%
Thiamin (as thiamine mononitrate)	3 mg	176%
Riboflavin	3 mg	150%
Vitamin B_6 (as pyridoxine HCl)	20 mg	800%
Folic Acid	1 mg	125%
Vitamin B_{12} (as cyanocobalamin)	15 mcg	188%
Iron (as ferrous fumarate)	28 mg	156%
Magnesium (as magnesium oxide)	30 mg	7%
Zinc (as zinc oxide)	20 mg	133%
Copper (as cupric sulfate)	1 mg	50%
Omega-3 Fatty Acids (DHA-EPA)	200 mg	*

* Daily Value not established

Other Ingredients: Gelatin, Glycerin, Soybean Oil, Beeswax, Purified Water, Soy Lecithin, Natural Creamy Orange Flavor, Annatto Powder, Titanium Dioxide, and Ethyl Vanillin. **Contains Fish Oil and Soy.**

KEEP THIS OUT OF REACH OF CHILDREN

CONTRAINDICATIONS

Virt-Nate DHA should not be used by patients with known history of hypersensitivity to any of its 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.

CAUTIONS

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).

Concurrent use of folic acid has been associated with enhanced phenytoin metabolism, lowering the level of the AED in the blood and allowing breakthrough seizures to occur. Caution should be used when prescribing this product among patients who are receiving treatment with phenytoin or other anticonvulsants.

Exercise caution with the concomitant use of folinic acid and trimethoprim-sulfamethoxazole for the acute treatment of Pneumocystis carinii pneumonia in patients with HIV infection as it is associated with increased rates of treatment failure and mortality in a placebo controlled study.

The action of levodopa is antagonized by pyridoxine.

Products containing iron should not be used during dimercaprol therapy. Dimercaprol can bind to iron and cause kidney damage.

Avoid administering omega-3 fatty acids to patients with inherited or acquired predisposition toward bleeding, including patients taking anticoagulants. Exercise caution with these patients to ensure that the prescribed dosage of DHA does not exceed 1 gram (1000 mg) per day.

SIDE EFFECTS

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

Iron can cause mild gastrointestinal side effects, particularly when taken on an empty stomach.

DRUG INTERACTIONS

Folic Acid

Concurrent use of folic acid has been associated with enhanced phenytoin metabolism, lowering the level of the AED in the blood and allowing breakthrough seizures to occur.

Folinic acid may enhance the toxicity of fluorouracil.

High levels of folic acid may result in decreased serum levels of pyrimethamine.

Concurrent administration of chloramphenicol and folinic acid in folate-deficient patients may result in antagonism of the hematopoietic response to folate.

Antiepileptic drugs (including, but not limited to, phenytoin, carbamazepine, primidone, valproic acid, fosphenytoin, valproate, phenobarbital and lamotrigine) have been shown to impair folate absorption and increase the metabolism of circulating folate.

Fluoxetine

Fluoxetine exerts a noncompetitive inhibition of the 5-methyltetrahydrofolate active transport system in the intestine.

Decreased folic acid levels have been reported to be associated with the administration of Cholestyramine, Colestipol, Cycloserine, Dihydrofolate Reductase Inhibitors (aminopterin, methotrexate, pyrimethamine, triamterene, and trimethoprim), L-dopa, colchicine, oral contraceptives, methylprednisolone, pancreatic extracts (pancreatin, pancrelipase), prolonged intravenous pentamidine, smoking and alcohol consumption, sulfasalazine, metformin, heme iron, isotretinoin, and after a 6-month course of therapy, warfarin can produce a significant impairment of folate status.

Thiamin (Vitamin B_1)

Furosemide, a loop diuretic, can decrease thiamin levels.

There have been case reports that fluorouracil may increase thiamin metabolism.

Vitamin B_6

Vitamin B_6 should not be given to patients receiving the drug levodopa because the action of levodopa is antagonized by Vitamin B_6. However, Vitamin B_6 may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa.

Isoniazid can produce a Vitamin B_6 deficiency.

Vitamin B_{12}

Antibiotics, cholestyramine, colchicine, colestipol, metformin, para-aminosalicylic acid, and potassium chloride may decrease the absorption of vitamin B_{12}, and nitrous oxide can produce a functional vitamin B_{12} deficiency.

Vitamin D_3

Some thiazide diuretics, such as hydrochlorothiazide, as well as antacids, bile acid sequestrants (such as cholestyramine), mineral oil, orlistat, olestra, cimetidine, and anticonvulsant medications may reduce the absorption or increase the catabolism of Vitamin D.

Vitamin D supplementation should not be given with calcium to patients with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism or those who form calcium-containing kidney stones.

Iron

Iron supplements might reduce the amounts of levodopa available to the body and diminish its clinical effectiveness.

Levothyroxine ingested simultaneously with iron can result in clinically significant reductions in levothyroxine efficacy.

Proton pump inhibitors reduce the acidity of stomach contents and can reduce iron absorption.

Zinc

Zinc may decrease absorption of quinolone or tetracycline antibiotics.

Cupric oxide

Concomitant use of penicillamine and copper can cause decreased absorption of both substances.

Omega-3 Fatty Acids

Ingestion of more than 3 grams per day of omega-3 fatty acids (ALA, EPA, and DHA) may have potential antithrombotic effects, and may increase bleeding times.

Avoid administering omega-3 fatty acids to patients with inherited or acquired predisposition toward bleeding, including patients taking anticoagulants. Exercise caution with these patients to ensure that the

prescribed dosage of DHA does not exceed 1 gram (1000 mg) per day.

PREGNANT AND NURSING MOTHERS

Virt-Nate DHA is a prescription folate dietary supplement formulated for use before, during and/or after pregnancy regardless of lactation status.

KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.

HEALTH CLAIM

Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord defect.

HOW SUPPLIED

Virt-Nate DHA is supplied as annatto colored softgel, imprinted with "V370," dispensed in bottles of 30 softgels.

STORAGE

Store at controlled room temperature 15° to 30°C (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 1-888-848-3593 or FDA at 1-800-FDA-1088.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

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Manufactured for
Virtus Pharmaceuticals, LLC
Tampa, FL 33619
1-888-848-3593

Made in Canada
Rev. 12/2015

PRINCIPAL DISPLAY PANEL - 30 Softgel Bottle Label

VIRTUS
PHARMACEUTICALS

69543-**370**-30

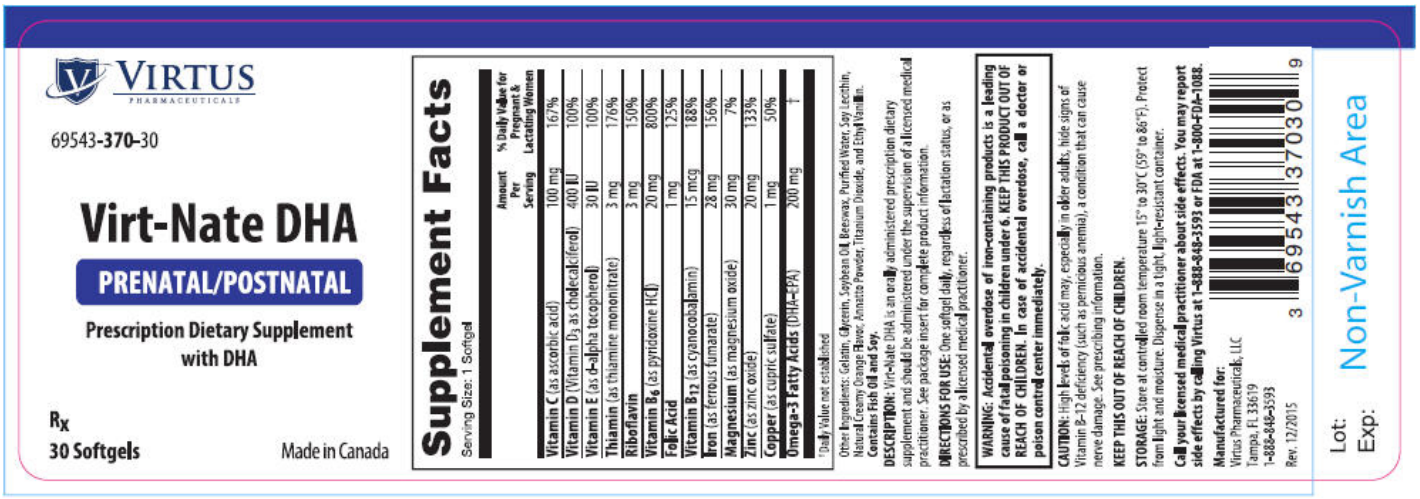
Virt-Nate DHA

PRENATAL/POSTNATAL

Prescription Dietary Supplement
with DHA

R_x
30 Softgels

Made in Canada



VIRT-NATE DHA

ascorbic acid, cholecalciferol, .alpha.-tocopherol, d-, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, folic acid, cyanocobalamin, ferrous fumarate, magnesium oxide, zinc oxide, cupric sulfate, and omega-3 fatty acids capsule

Product Information			
Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:69543-370
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL, D-	30 [iU]
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3 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	15 ug
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	28 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	30 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	20 mg
CUPRIC SULFATE (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	1 mg
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S) (OMEGA-3 FATTY ACIDS - UNII:71M78END5S)	OMEGA-3 FATTY ACIDS	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SOYBEAN OIL (UNII: 241ATL177A)	

YELLOW WAX (UNII: 2ZA36H0S2V)	
WATER (UNII: 059QF0KO0R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69543-370-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		01/12/2016	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	14 mm	
imprint		

Labeler - Virtus Pharmaceuticals (079659493)

Revised: 1/2016 Virtus Pharmaceuticals