

VIRT-PN PLUS- ascorbic acid, cholecalciferol, .alpha.-tocopherol, pyridoxine, levomefolic acid, folic acid, cyanocobalamin, biotin, calcium carbonate, ferrous fumarate, potassium iodide, magnesium oxide, doconexent, and icosapent capsule, gelatin coated
Virtus Pharmaceuticals

Virt-PN Plus

Prenatal/Postnatal Prescription Dietary Supplement

69543-243-30

R_x

DESCRIPTION

Virt-PN Plus is a prescription prenatal/postnatal multivitamin/mineral dietary supplement with an essential fatty acid and should be administered under the supervision of a licensed medical practitioner.

DIRECTIONS FOR USE

Before, during, and/or after pregnancy, 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	85 mg	142%
Vitamin D (Vitamin D ₃ as cholecalciferol)	200 IU	50%
Vitamin E	10 IU	33%
Vitamin B₆	25 mg	1000%
Folate (L-methylfolate, or 6(S)-5-MTHF 600 mcg) (Folic acid, USP 400 mcg)	1 mg	125%
Vitamin B₁₂	12 mcg	150%
Biotin	250 mcg	83%
Calcium (calcium carbonate)	140 mg	11%
Iron (ferrous fumarate)	28 mg	156%
Iodine (potassium iodide)	150 mcg	100%
Magnesium (magnesium oxide)	45 mg	10%
Docosahexaenoic Acid (DHA)	300 mg*	†
Elcosapentaenoic Acid (EPA)	40 mg*	†

* From at least 340 mg omega-3s from at least 390 mg purified fish oils.

† Daily Value not established

Other Ingredients: Gelatin (Bovine), Glycerin, DI Water, Yellow Beeswax, Lecithin, Soybean Oil, Titanium Dioxide, FD&C Yellow #5, and FD&C Blue #1.

Contains FD&C Yellow #5, FD&C Blue #1, fish and soy.

ALLERGY STATEMENT

This product has been manufactured in a facility that also manufactures products containing tree nuts, peanuts, fish, egg, wheat, milk, soy and shellfish. Individuals with allergic tendencies to these substances should use discretion.

KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN.

CONTRAINDICATIONS

This product is contraindicated in patients with a known hypersensitivity to any of the components contained in this product. This product is contraindicated for individuals with conditions for which any of the ingredients are contraindicated.

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).

Patients undergoing cancer treatment should consult their licensed medical practitioner for advice.

Caution should be exercised when using folate with folate antagonists (e.g. methotrexate, trimethoprim). Patients should not be given folate simultaneously with a folate antagonist for the purpose of reducing or preventing clinical toxicity, as the therapeutic effect of the antagonist may be nullified. Exercise caution with the concomitant use of folate and trimethoprim-sulfamethoxazole for the acute treatment of *Pneumocystis carinii* pneumonia in patients with HIV infection as this has been associated with increased rates of treatment failure and mortality.¹

Folinic acid may enhance the toxicity of fluorouracil. Deaths from severe enterocolitis, diarrhea, and dehydration have been reported in elderly patients receiving weekly formyl-tetrahydrofolate and fluorouracil; accompanying granulocytopenia and fever were present in some but not all of the patients.

The concomitant use of formyl-tetrahydrofolate with trimethoprim-sulfamethoxazole for the acute treatment of *Pneumocystis carinii* pneumonia in patients with HIV infection was associated with increased rates of treatment failure and mortality in a placebo controlled study.¹

Caution is recommended in patients with a history of bipolar illness as mood elevation is possible following coadministration of folate with antidepressant therapy.

Caution is recommended in patients taking anticonvulsant medications, because folate may lower seizure threshold. Furthermore, it has been reported that anticonvulsant medications interfere with folate metabolism.

Ingestion of more than 2 grams per day of omega-3 fatty acids (ALA, EPA, and DHA) as dietary supplements may have antithrombotic effects and may increase bleeding times. Administration of omega-3 fatty acids, including DHA, should be avoided in patients with inherited or acquired bleeding predisposition, including those taking anticoagulants.

SIDE EFFECTS

Allergic reactions have been reported following the use of oral folate.

Vitamin B₁₂ (cobalamin) has a remarkably low potential for side effects.

Paresthesia, somnolence, nausea and headaches have been reported with Vitamin B₆ (pyridoxine).

Call your medical practitioner about side effects.

DRUG INTERACTIONS

Drug interactions with folate include

- Folate may decrease serum levels of first generation anticonvulsants (carbamazepine, fosphenytoin, phenytoin, phenobarbital, primidone, valproic acid, valproate).
- Folic acid absorption (and consequent reduction in serum folate levels) may be reduced by cholestyramine, colestipol, and cycloserine. Fluoxetine exerts a noncompetitive inhibition of the 5-methyltetrahydrofolate active transport in the intestine. Sulfasalazine inhibits absorption and metabolism of folic acid.
- Plasma folate levels may be decreased by colchicine, levodopa, dihydrofolate reductase inhibitors (including aminopterin, methotrexate, pyrimethamine, triamterene, and trimethoprim). Serum folate levels may be depressed by smoking and/or drinking alcohol, oral contraceptive therapy, methylprednisolone, and metformin treatment of patients with type 2 diabetes. Reduced folate levels have occurred in some patients taking pancreatic extracts (e.g. pancreatin and pancrelipase), isotretinoin, or prolonged intravenous pentamidine.
- Folate may enhance the toxicity of fluorouracil.
- Concurrent administration of chloramphenicol and folate in folate-deficient patients may result in antagonism of the hematopoietic response to folate.

Drug interactions with Vitamin B₆ include

- Cycloserine increases urinary excretion of pyridoxine, which may exacerbate seizures and neurotoxicity associated with cycloserine.
- Some antiepileptic medications, including valproic acid, carbamazepine, and phenytoin, increase the catabolism rate of Vitamin B₆. This can result in increased homocysteine levels, which in antiepileptic drug users can increase the risk of epileptic seizures and vascular events like stroke.
- Theophylline is associated with low pyridoxal 5' phosphate concentrations, which could contribute to neurological and central nervous system side effects associated with theophylline use.
- Vitamin B₆ should not be given to patients receiving the drug levodopa because the action of levodopa may be antagonized by Vitamin B₆. Vitamin B₆ may or may not interfere with levodopa even when used concurrently with carbidopa.

Drug interactions with Vitamin B₁₂ include

- Arsenic trioxide, an antineoplastic drug, can cause QT interval prolongation and complete atrioventricular block; theoretically, use of arsenic trioxide during intensive Vitamin B₁₂ treatment may potentiate risk of cardiac arrhythmias, because of the hypokalemia that may develop during the early phase of Vitamin B₁₂ therapy.
- Metformin may reduce the absorption of Vitamin B₁₂ through alterations in gastric motility, bacterial overgrowth, or alterations in calcium-dependent intestinal uptake of the Vitamin B₁₂ intrinsic factor complex.
- Chloramphenicol may interfere with Vitamin B₁₂ activity.

SPECIFIC POPULATIONS

Pregnant/Nursing Women

Virt-PN Plus is specially formulated for pregnant and nursing women and should not be given to children.

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

HOW SUPPLIED

Supplied as oblong, green softgel imprinted "243," dispensed in bottles of 30 softgels.

STORAGE

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.

Call your 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.

REFERENCES

1. Safrin S, Lee BL, Sande MA. Adjunctive folinic acid with trimethoprim-sulfamethoxazole for Pneumocystis carinii pneumonia in AIDS patients is associated with an increased risk of therapeutic failure and death. *J Infect Dis.* 1994 Oct; 170(4):912-7.
2. De-Regil LM, Fernández-Gaxiola AC, Dowswell T, et al. Effects and safety of periconceptional folate supplementation for preventing birth defects. *Cochrane Database Syst Rev.* 2010 Oct 6;(10): CD007950. doi: 10.1002/14651858.CD007950.pub2.
3. Letter Regarding Dietary Supplement Health Claim for Folic Acid With Respect to Neural Tube Defects (Docket No. 91N-100H). October 10, 2000.
4. Hendler SS, Rorvik D. *PDR for Nutritional Supplements.* 2nd ed. Montvale, NJ. Physicians' Desk Reference Inc; 2008.5.
10. Code of Federal Regulations Title 21 Section 172.345.
11. Code of Federal Regulations Title 21 Section 101.9(j)(8).
12. Letter Regarding Dietary Supplement Health Claim for Folic Acid, Vitamin B6, and Vitamin B12 and Vascular Disease (Docket No. 99P-3029). November 28, 2000.
13. Hallert C, Tobiasson P, Walan A. Serum folate determinations in tracing adult coeliacs. *Scand J Gastroenterol.* 1981;16:263-67.
14. Wu A, Chanarin I, Levi AJ. Macrocytosis of chronic alcoholism. *The Lancet.* 1974;1:829-31.

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Manufactured for

Virtus Pharmaceuticals, LLC
Tampa, Florida 33619
1-888-848-3593

Made in USA
Rev. 10/2015

PRINCIPAL DISPLAY PANEL - 30 Softgels Bottle Label

VIRTUS

PHARMACEUTICALS

69543-243-30

Virt-PN Plus

PRENATAL/POSTNATAL

Prescription Dietary Supplement

R_x
30 Softgels
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Manufactured for:
 Virtus Pharmaceuticals, LLC
 Tampa, Florida 33619
 1-888-948-3593
 Rev. 10/2015

Lot:
 Exp:

VIRT-PN PLUS

ascorbic acid, cholecalciferol, .alpha.-tocopherol, pyridoxine, levomefolic acid, folic acid, cyanocobalamin, biotin, calcium carbonate, ferrous fumarate, potassium iodide, magnesium oxide, doconexent, and icosapent capsule, gelatin coated

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69543-243
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 (UNII: H4N855PNZ1) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL	10 [iU]
PYRIDOXINE (UNII: KV2JZ1BI6Z) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	25 mg
LEVOMEFOLIC ACID (UNII: 8S95DH25XC) (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
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	250 ug
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	140 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	28 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	150 ug
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	45 mg
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	300 mg
ICOSAPENT (UNII: AAN7QOV9EA) (ICOSAPENT - UNII:AAN7QOV9EA)	ICOSAPENT	40 mg

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SOYBEAN OIL (UNII: 241ATL177A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69543-243-30	30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		12/08/2015	

Supplement Facts	
Serving Size :	Serving per Container :
Amount Per Serving	% Daily Value
color	
scoring	1
shape	
size (solid drugs)	24 mm

imprint

Labeler - Virtus Pharmaceuticals (079659493)

Revised: 12/2015

Virtus Pharmaceuticals