

VIRT-GARD- pyridoxine hydrochloride, folic acid, and cyanocobalamin tablet
Virtus Pharmaceuticals

Virt-Gard

76439-353-10

Rx

**Prescription Folic Acid-Containing
Dietary Supplement**

DESCRIPTION

Virt-Gard is an orally administered prescription dietary supplement and should be administered under the supervision of a licensed medical practitioner.

Supplement Facts		
Serving Size: 1 Tablet		
	Amount Per Serving	% Daily Value*
Vitamin B₆ (Pyridoxine HCl)	25 mg	1471%
Folate (2200 mcg Folic Acid)	3667 mcg DFE	917%
Vitamin B₁₂ (Cyanocobalamin)	1 mg	41667%

*Percent Daily Values are based on a 2,000 calorie diet.

Other Ingredients: Dicalcium Phosphate, Microcrystalline Cellulose, Pregelatinized Starch, Pink Coating (Hypromellose, Polydextrose, Titanium Dioxide, Talc, Maltodextrin, Medium Chain Triglycerides, FD&C Red #40, FD&C Yellow #6, FD&C Blue #1), Stearic Acid, Silicon Dioxide, Magnesium Stearate.

INDICATIONS AND USAGE

Virt-Gard tablets are indicated for nutritional support and folic acid supplementation. This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

CONTRAINDICATIONS

This product is contraindicated in people with known history of hypersensitivity to any of the ingredients.

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).

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

SIDE EFFECTS

Allergic sensitization has been reported following oral administration of folic acid. Paresthesia, somnolence, nausea and headaches have been reported with pyridoxine hydrochloride.

Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body have been associated with cyanocobalamin.

DIRECTIONS FOR USE (Adults)

1 tablet daily or as directed by a licensed medical practitioner.

HOW SUPPLIED

Supplied as round, pink tablets imprinted with "V353," dispensed in bottles of 100 tablets.

76439-353-10

STORAGE

Store at controlled room temperature 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 1-855-255-6076.

KEEP OUT OF REACH OF CHILDREN.

Rx

Manufactured for:

Virtus Pharmaceuticals OPCO II, LLC

Nashville, TN 37217

1-855-255-6076

Made in USA

Rev. 06/2018

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label



76439-353-10

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Rx
100 Tablets

Made in USA

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DIRECTIONS FOR USE (Adults): 1 tablet daily or as directed by a licensed medical practitioner.

CAUTION: High levels of folic acid may hide signs of B-12 deficiency, such as pernicious anemia. See package insert for more information.

PRECAUTIONS, CONTRAINDICATIONS, SIDE EFFECTS: See package insert for more information.

KEEP OUT OF REACH OF CHILDREN.

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Lot:
Exp:

VIRTUS®
PHARMACEUTICALS OPCO II

76439-353-10

Virt-Gard

**Prescription Folic Acid-Containing
Dietary Supplement**

R_x
100 Tablets
Made in USA

VIRT-GARD

pyridoxine hydrochloride, folic acid, and cyanocobalamin tablet

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:76439-353
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE	25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	2.2 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	1 mg

Inactive Ingredients

Ingredient Name	Strength
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NHRIC:76439-353-10	100 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Dietary Supplement		09/30/2015		

Supplement Facts		
Serving Size :	Serving per Container :	
	Amount Per Serving	% Daily Value
color		
size (solid drugs)	10 mm	
shape		
scoring	1	
imprint		

Labeler - Virtus Pharmaceuticals (079659493)

Revised: 12/2019

Virtus Pharmaceuticals