

**VIRT-CAPS- ascorbic acid, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, biotin, and calcium pantothenate capsule**  
**Virtus Pharmaceuticals**

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**Virt-Caps**

**69543-260-10**

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

Prescription Dietary Supplement

**DESCRIPTION**

Virt-Caps is an orally administered prescription vitamin B dietary supplement formulated for the dietary management of persons who require increased amounts of folic acid and pyridoxine; it also includes vitamin C. Virt-Caps should be administered under the supervision of a licensed medical practitioner.

<b>Supplement Facts</b>		
<b>Serving Size: 1 Softgel</b>		
	<b>Amount Per Serving</b>	<b>% Daily Value</b>
<b>Vitamin C</b> (as ascorbic acid)	100 mg	167%
<b>Thiamine</b> (as thiamine mononitrate)	1.5 mg	100%
<b>Riboflavin</b>	1.7 mg	100%
<b>Niacin</b> (as niacinamide)	20 mg	100%
<b>Vitamin B<sub>6</sub></b> (as pyridoxine HCl)	10 mg	500%
<b>Folic Acid</b>	1 mg	250%
<b>Vitamin B<sub>12</sub></b> (as cyanocobalamin)	6 mcg	100%
<b>Biotin</b>	150 mcg	50%
<b>Pantothenic Acid</b> (as calcium pantothenate)	5 mg	50%

Other Ingredients: Soybean Oil, Gelatin, Glycerin, Water, Bees Wax, Lecithin, Titanium Dioxide, FD&C Yellow #6, FD&C Red #40, and FD&C Blue #1.

**Contains Soy, FD&C Yellow #6, FD&C Red #40 and FD&C Blue #1.**

**Side Effects**

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

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

Paresthesia, somnolence, nausea, and headaches have been reported with pyridoxine.

**KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN.**

**INTERACTIONS**

*Drugs which may interact with folate include but are not limited to:*

- First generation anticonvulsants (folate may reduce their effectiveness)
- Capecitabine (folate may enhance its toxicity)
- Fluorouracil (folate may enhance its toxicity)

*Drugs that may interfere with folate metabolism include, but are not limited to:*

- Dihydrofolate Reductase Inhibitors
- Fluoxetine
- Nonsteroidal Anti-inflammatory Drugs
- Sulfasalazine
- Warfarin

*Drugs which may interfere with the absorption of folate from the gastrointestinal tract or decrease plasma levels include, but are not limited to:*

- Cholestyramine
- Colestipol
- Colchicine
- Levodopa
- Cycloserine
- Isotretinoin
- Oral Contraceptives
- Methylprednisolone
- Pancreatic Enzymes
- Pentamidine
- Smoking and Alcohol
- Sulfasalazine
- Metformin

*Drugs which may interact with vitamin B<sub>6</sub> include, but are not limited to:*

- Levodopa (the action of levodopa may be antagonized by vitamin B<sub>6</sub>.)

*Drugs which may interact with vitamin B<sub>12</sub> include, but are not limited to:*

- Antibiotics, cholestyramine, colchicine, colestipol, metformin, para-aminosalicylic acid, and potassium chloride (may decrease the absorption of vitamin B<sub>12</sub>)
- Nitrous oxide (can produce a functional vitamin B<sub>12</sub> deficiency)

## **CONTRAINDICATIONS**

This product is contraindicated in patients with a known hypersensitivity to any of its components.

## **CAUTION**

**High levels of folic acid may, especially in older adults, hide signs of vitamin B<sub>12</sub> deficiency (such as pernicious anemia), a condition that can cause nerve damage.**

## **PREGNANCY and NURSING MOTHERS**

This product contains only B and C vitamins and is not intended for use as a prenatal/postnatal multivitamin.

## **DIRECTIONS FOR USE**

One softgel daily or as directed by a licensed medical practitioner.

## **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. Notice: Contact with moisture may produce surface discoloration or erosion.

## HOW SUPPLIED

Virt-Caps is supplied as black softgels imprinted on one side with "V260" dispensed in child-resistant bottles of 100 softgels

69543-260-10

## KEEP THIS OUT OF REACH OF CHILDREN.

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

**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.**

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

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

MADE IN USA

Rev. 06/2015

## PRINCIPAL DISPLAY PANEL - 100 Capsule Bottle Label

**VIRTUS**  
PHARMACEUTICALS



69543-260-10

**Virt-Caps**

Prescription Dietary Supplement

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

**100 Softgels**  
**Made in USA**

 69543-260-10	<b>Supplement Facts</b>		<b>DESCRIPTION:</b> Virt-Caps is an orally administered prescription vitamin B dietary supplement formulated for the dietary management of persons who require increased amounts of folic acid and pyridoxine; it also includes vitamin C. Virt-Caps should be administered under the supervision of a licensed medical practitioner. <b>DIRECTIONS FOR USE:</b> One softgel daily or as directed by a licensed healthcare practitioner. <b>CONTRAINDICATIONS:</b> See Professional Information. <b>CAUTION:</b> High levels of folic acid may, especially in older adults, hide signs of vitamin B <sub>12</sub> deficiency (such as pernicious anemia), a condition that can cause nerve damage. <b>SIDE EFFECTS:</b> See Professional Information. <b>KEEP THIS OUT OF REACH OF CHILDREN.</b> <b>STORAGE:</b> 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. <b>Call your licensed medical practitioner about side effects. You may report side effects by calling Virtus 1-888-848-3593 or FDA at 1-800-FDA-1088.</b>	
	Serving Size: 1 Softgel			
<b>Virt-Caps</b> Prescription Dietary Supplement	<b>Amount Per Serving</b>	<b>% Daily Value</b>	<b>Manufactured for:</b> Virtus Pharmaceuticals, LLC Tampa, Florida 33619 1-888-848-3593 Rev. 06/15	
	Vitamin C (as ascorbic acid)	100 mg		167%
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	Biotin	150 mcg		50%
	Pantothenic Acid (as calcium pantothenate)	5 mg		50%
<b>R<sub>x</sub></b> <b>100 Softgels</b>	<b>Made in USA</b>	Other Ingredients: Soybean Oil, Gelatin, Glycerin, Water, Bees Wax, Lecithin, Titanium Dioxide, FD&C Yellow #6, FD&C Red #40, and FD&C Blue #1. Contains Soy, FD&C Yellow #6, FD&C Red #40, and FD&C Blue #1.	 3 69543 26010 5	<b>Lot:</b> <b>Exp:</b>

## VIRT-CAPS

ascorbic acid, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, biotin, and calcium pantothenate capsule

### Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:69543-260
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.5 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.7 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	10 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	6 ug
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	150 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737, CALCIUM CATION - UNII:2M83C4R6ZB)	PANTOTHENIC ACID	5 mg

### Inactive Ingredients

Ingredient Name	Strength
SOYBEAN OIL (UNII: 241ATL177A)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69543-260-10	100 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		08/14/2015	

**Supplement Facts****Serving Size :****Serving per Container :**

	<b>Amount Per Serving</b>	<b>% Daily Value</b>
color		
scoring	1	
shape		
size (solid drugs)	15 mm	
imprint		

**Labeler** - Virtus Pharmaceuticals (079659493)

Revised: 8/2015

Virtus Pharmaceuticals