CORVITE FE- calcium ascorbate, cholecalciferol, pyridoxine hydrochloride, folic acid, 5-methyltetrahydrofolic acid, cyanocobalamin, iron pentacarbonyl, magnesium malate, zinc glycinate, calcium threonate tablet, coated
Vertical Pharmaceuticals, LLC

CORVITE® FE
Iron Supplement

SUPPLEMENT FACTS

Supplement Facts

Serving Size: 1 Tablet
Servings per Box: 30

	Amount per Serving	%DV for Adults and Children ≥4 years	% DV for Pregnant and Lactating Women
Total Carbohydrate	< 1 g	<1%*	<1%*
Vitamin C (Calcium Ascorbate) ‡	160 mg	178%	133%
Vitamin D (Cholecalciferol)	25 mcg (1000 IU)	125%	167%
Vitamin B_6 (Pyridoxine HCl)	10 mg	588%	500%
Folate [as folic acid 700 mcg and Quatrefolic® ((6S)-5-Methyltetrahydrofolic Acid) 300 mcg, (equivalent to 600 mcg of (6S)-5-Methyltetrahydrofolic Acid, Glucosamine Salt)]**	1667 mcg DFE	417%	278%
Vitamin B_{12} (Cyanocobalamin)	15 mcg	625%	536%
Iron (as Ferronyl® Carbonyl Iron)	150 mg	833%	556%
Magnesium (as Di-Magnesium Malate)***	15 mg	4%	4%
Zinc (as TRAACS® Zinc Glycinate Chelate)***	25 mg	227%	192%
Calcium Threonate‡	5 mg	†	†

* Percent Daily Values are based on a 2,000 calorie diet
† Daily Value (DV) not established
‡ (Acid metabolites – such as L-threonic acid, help with absorption of Vitamin C)

Other Ingredients: Microcrystalline Cellulose, di-Calcium Phosphate, Pregelatinized Starch, Red Color Coating (Hydroxypropylmethyl Cellulose, Polyvinyl Alcohol, FD&C Red #40 Lake, Glycerol Triacetate, Titanium Dioxide, Talc, FD&C Yellow #6 Lake, FD&C Blue #2 Lake), Croscarmellose Sodium, Magnesium Stearate, Silicon Dioxide and Fumed Silica.

VEGETARIAN FRIENDLY

GLUTEN, LACTOSE AND SUGAR FREE

CORVITE® FE is a professionally prescribed hematinic multivitamin/multimineral dietary supplement used to improve the nutritional status of patients with iron deficiency; this includes women prior to conception, throughout pregnancy, and in the postnatal period for both lactating and non-lactating mothers.

Other Ingredients: Microcrystalline Cellulose, DiCalcium Phosphate, Croscarmellose Sodium, Acacia, Isopropyl Alcohol, Povidone K30, Purified Water, Magnesium Stearate, TriPotassium Citrate, Citric Acid, Fumed Silica, Hypromellose, Ethyl Cellulose, Titanium Dioxide, Polyethylene Glycol, FD&C Red #40 Lake, Talc, Polysorbate 80, Hydroxypropyl Cellulose, Black Iron Oxide and Vegetable Oil.

CONTRAINDICATIONS

CORVITE®FE should not be used by patients with a known hypersensitivity to any of the listed ingredients. All iron compounds are contraindicated in patients with hemochromatosis, hemosiderosis, or hemolytic anemias.

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.

PRECAUTIONS

General: Do not exceed recommended dose. The type of anemia and the underlying cause or causes should be determined before starting therapy with CORVITE® FE. Since the anemia may be a result of a systemic disturbance, such as recurrent blood loss, the underlying cause or causes should be corrected, if possible.

Folic Acid: Folic acid alone is an improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurologic manifestations remain progressive. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

The patient’s medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

Pediatric Use: Safety and effectiveness in pediatric population have not been established.

Geriatric Use: Safety and effectiveness in elderly population have not been established.

DRUG INTERACTIONS

There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g., Aspirin, Heparin, Clopidogrel).

ADVERSE REACTIONS

Adverse reactions with iron therapy may include constipation, diarrhea, nausea, vomiting, dark stools and abdominal pain which are usually transient.

OVERDOSAGE

The clinical course of acute iron overdosage can be variable. Initial symptoms may include abdominal pain, nausea, vomiting, diarrhea, tarry stools, melena, hematemesis, hypotension, tachycardia, metabolic acidosis, hyperglycemia, dehydration, drowsiness, pallor, cyanosis, lassitude, seizures, shock and coma.

DESCRIPTION

CORVITE®FE is a red, oval shaped, bisected tablet imprinted with “VP060”.

DIRECTIONS FOR USE

Take one tablet by mouth daily or as directed by a physician.

HOW SUPPLIED

CORVITE®FE is available in bottles of 30 tablets.

Product Code: 68025-060-30

STORAGE

Store at controlled room temperature 15°-30°C (59°-86°F) [See USP]. Protect from light, moisture and avoid excessive heat. Dispense in a tight, light resistant container as defined by the USP using a child-resistant closure.

KEEP OUT OF REACH OF CHILDREN.

**** Quatrefolic® is a registered trademark of Gnosis, SpA.**
U.S. Patent No. 7,947,662.

*****TRAACS® is a registered trademark of Albion International, Inc.**
Malate covered by U.S. Patent No, 6,706,904;
Chelate covered by U.S. Patent No. 7,838,042.

Call your doctor about side effects. To report side effects, call Vertical Pharmaceuticals at 1-877-95-VERTI (1-877-958-3784) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Customer Service: 1-866-600-4799 **Rev. 08/2018**

Distributed by:
Vertical Pharmaceuticals, LLC
Bridgewater, NJ 08807
www.verticalpharma.com

VERTICAL PHARMACEUTICALS, LLC

PRINCIPAL DISPLAY PANEL - 30 Tablet Bottle Label

68025-060-30

CORVITE® *FE*
Iron Supplement
Tablets

Multivitamin/Multimineral

Gluten, Lactose, and Free
Vegetarian Friendly

30 Tablets

VERTICAL
PHARMACEUTICALS, LLC

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DESCRIPTION
CORVITE®FE is a red, oval-shaped, bisected tablet imprinted with "FE060".

DIRECTIONS FOR USE
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HOW SUPPLIED
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Product Code: 68025-060-30

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Distributed by:
Vertical Pharmaceuticals, LLC
Bridgewater, NJ 08807
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VERTICAL PHARMACEUTICALS, LLC

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Lift Here for entire Product Information
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3 68025-060-30 1

CORVITE® FE IRON SUPPLEMENT

Supplement Facts
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Servings per Box: 30

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CORVITE FE

calcium ascorbate, cholecalciferol, pyridoxine hydrochloride, folic acid, 5-methyltetrahydrofolic acid, cyanocobalamin, iron pentacarbonyl, magnesium malate, zinc glycinate, calcium threonate tablet, coated

Product Information

Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:68025-060
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Calcium Ascorbate (UNII: 183E4W213W) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	160 mg
Calcium Threonate (UNII: HBB4YPO93U) (Calcium Cation - UNII:2M83C4R6ZB)	Calcium Threonate	5 mg
Cholecalciferol (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	1000 [iU]
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	10 mg
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	15 ug
Magnesium Malate (UNII: LA9X9UJA2Z) (Magnesium Cation - UNII:T6V3LHY838)	Magnesium Cation	15 mg
Zinc Glycinate (UNII: 681VJX72FE) (Zinc Cation - UNII:13S1S8SF37)	Zinc Cation	25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	700 ug
5-METHYLTETRAHYDROFOLIC ACID (UNII: TYK22LML8F) (FOLIC ACID - UNII:935E97BOY8)	5-METHYLTETRAHYDROFOLIC ACID	300 ug
IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	150 mg

Inactive Ingredients

Ingredient Name	Strength
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
Magnesium Stearate (UNII: 70097M6I30)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Hypromelloses (UNII: 3NXW29V3WO)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
Talc (UNII: 7SEV7J4R1U)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
STARCH, CORN (UNII: O8232NY3SJ)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
TRIACETIN (UNII: XHX3C3X673)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:68025-060-30	30 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		09/19/2013	

Supplement Facts		
Serving Size :		**Serving per Container :**
	Amount Per Serving	**% Daily Value**
color		
imprint		
scoring	2	
shape		
size (solid drugs)	19 mm	

Labeler - Vertical Pharmaceuticals, LLC (173169017)

Revised: 8/2018 Vertical Pharmaceuticals, LLC