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) 2	5 mcg (1000 IU)	125%	167%
Vitamin B ₆ (Pyridoxine HCI)	10 mg	588%	500%
Folate	1667 mcg DFE	417%	278%
[as folic acid 700 mcg and Quatrefolic ((6S)-5-Methyltetrahydrofolic Acid) 30 (equivalent to 600 mcg of (6S)-5-Methyltetrahydrofolic Acid, Glucosami	0 mcg,		
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 Che	late)*** 25 mg	227%	192%
Calcium Threonate [‡]	5 mg	t	t
* Percent Daily Values are based on a † Daily Value (DV) not established ‡ (Acid metabolites – such as L-threoni			of Vitamin

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

C)

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

 $\mathsf{CORVITE}^{\$}$ FE is not recommended for and should not be given to patients receiving levodopa because the action of levodopa is antagonized by pyridoxine. 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 1-770-509-4500 or FDA at 1-800-FDA-1088 or

www.fda.gov/medwatch.

PLR-CFE-00003-1 12/2021

Rev.

Distributed by: Vertical Pharmaceuticals, LLC Alpharetta, GA 30005 www.verticalpharma.com



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



CORVITE FE

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)	As corbic 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:KV2JZ 1BI6Z)	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)		

P	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: 1/2022 Vertical Pharmaceuticals, LLC