CORVITA 150- iron, folic acid, ascorbic acid, pyridoxine hydrochloride, cyanocobalamin and citrate tablet Trigen Laboratories, LLC

CORVITA [™] 150 TABLETS

SUPPLEMENT FACTS

Supplement Facts Serving Size: 1 Tablet Servings Per Box: 100						
	Amount per Serving	% Daily Value for Adults Only				
Vitamin C (as Ascorbic Acid)	120 mg	133%				
Vitamin B ₆ (as Pyridoxine HCI)	10 mg	588%				
Folate	2,083 mcg DFE (as 1,250 mcg Folic Acid)	521%				
Vitamin B ₁₂ (as Cyanocobalamin)	15 mcg	625%				
Iron (as Ferronyl [®] Carbonyl Iron)	150 mg	833%				
Zinc (as Zinc Citrate)	25 mg	227%				

Other Ingredients: Microcrystalline Cellulose, Pregelatinized Starch, Red Color Coating (Polyvinyl Alcohol, Polyethylene Glycol, FD&C Red #40 Lake, Talc, Titanium Dioxide), Croscarmellose Sodium, Magnesium Stearate, Stearic Acid

GLUTEN-, LACTOSE- AND SUGAR-FREE

CORVITA[™] 150 is a prescription multivitamin/multimineral supplement used to improve the nutritional status of patients with iron deficiency

CONTRAINDICATIONS

CORVITA[™] 150 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 CORVITA[™] 150. 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 B12 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 populations have not been established.

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

DRUG INTERACTIONS

CORVITA[™] 150 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. Adverse reactions with iron therapy 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

CORVITA[™] 150 is a red, oval bisected tablet imprinted with "VP031".

DIRECTIONS FOR USE

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

HOW SUPPLIED

CORVITA[™] 150 tablets are supplied in unit dose packs of 100 (10 blister cards of 10 tablets each).

PRODUCT CODE 13811-066-10

STORAGE

Store at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]. Protect from light and moisture and avoid excessive heat. Dispense in a tight, light resistant container as defined in the USP using a child-resistant closure.

KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.

For use on the order of a healthcare practitioner

Call your doctor about side effects. To report side effects, call Trigen Laboratories at 1-770-509-4500 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

PLR-CORVITA150-00001-1 Rev. 12/2021

Manufactured for: Trigen Laboratories, LLC Alpharetta, GA 30005



PRINCIPAL DISPLAY PANEL - 100 Tablets Blister Label

13811-066-10

CORVITA [™] 150 TABLETS

Iron Supplementation

Gluten-, Lactose-, and Sugar-Free



CORVITA 150

iron, folic acid, ascorbic acid, pyridoxine hydrochloride, cyanocobalamin and citrate tablet

Product Type		DIETARY SUPPLEMENT	Itom	Item Code (Source) NH		NHRIC-138	HRIC:13811-066	
						1111101200	INC.15011-000	
Route of Administ	ration	ORAL						
Active Ingredier	nt/Active	Moiety						
J		edient Name			Basis of S	trenath	Strenat	
Iron (UNII: E1UOL152H	n (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7) Iron					150 mg		
	Folic Acid (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8) Folic Acid					1.25 mg		
ascorbic acid (UNII: F	Q6CK8PD0F	(ASCORBIC ACID - UNI	I:PQ6CK8PD0	R)	ascorbic acid		120 mg	
pyridoxine Hydrochl	oride (UNII:	68Y4CF58BV) (PYRIDOX	(INE - UNII:KV2	JZ1BI6Z)	pyridoxine Hy	drochloride	10 mg	
Cyanocobalamin (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204) Cyanocobalamin						15 ug		
ZINC (UNII: J41CSQ7Q	DS) (ZINC -	UNII:J41CSQ7QDS)			ZINC		25 mg	
Inactive Ingredi	ents							
		Ingredient Nar	ne			St	Strength	
Cellulose, Microcrys	talline (UN	II: OP1R32D61U)					-	
		FIED (UNII: 532B59J990))					
POLYETHYLENE GLY	COL, UNSP	ECIFIED (UNII: 3WQ0SI	DW1A)					
FD&C RED NO. 40 (U	NII: WZ B912	7XOA)						
TALC (UNII: 7SEV7J4R1	LU)							
TITANIUM DIOXIDE (UNII: 15FIX9	/2JP)						
CROSCARMELLOSE S	ODIUM (UN	III: M28OL1HH48)						
MAGNESIUM STEARA	TE (UNII: 70	097M6I30)						
STEARIC ACID (UNII: 4	4ELV7Z65AP)						
STARCH, CORN (UNII:	O8232NY35	5J)						
Packaging								
# Item Code	Pack	age Description	Marketin	g Start	Date Ma	rketing E	nd Date	
1 NHRIC:13811-066-1		BLISTER PACK						
Marketing In	format	ion						
	Annlica	tion Number or Mo	nograph	Marke	ting Start	Marke	ting End	
Marketing Category	Арріїса	Citation	negraph		Date		ate	

Supplement Facts

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

Labeler - Trigen Laboratories, LLC (830479668)

Revised: 12/2021

Trigen Laboratories, LLC