CORVITE® FE Tablets

1-000-9721-00

PRESCRIBING INFORMATION

DESCRIPTION

Red, oval bisected tablets embossed "VP042".

Each tablet contains:

Sumalate™ (elemental iron)*	25 mg
Ferronyl® Carbonyl Iron (elemental iron)	125 mg
Folate	1 mg
Vitamin C (Calcium Ascorbate)	160 mg
Calcium Threonate	5 mg
Vitamin B_6 (Pyridoxine HCl)	10 mg
Vitamin B_{12} (Cyanocobalamin)	15 mcg
Vitamin D_3 (Cholecalciferol)	1,000 IU
Zinc (as TRAACS® zinc glycinate chelate)†	25 mg
Magnesium (as di-magnesium malate)†	15 mg

150 mg

*Sumalate™ (ferrous asparto glycinate) is a trademark of Albion International, Inc., Clearfield, Utah.

†DimaCal and TRAACS are registered trademarks of Albion Laboratories, Inc. Malates covered by U.S. Patent 6,706,904, chelate covered by U.S. Patent 7,838,042; and patents pending.

Inactive Ingredients

Black Iron Oxide, Citric Acid, Croscarmellose Sodium, Di Calcium Phosphate, Ethyl Cellulose, FD&C Red #40 Lake, Fumed Silica, Gum Arabic, Hydroxypropyl Cellulose, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polysorbate 80, PVP K30, Talc, Titanium Dioxide, TriPotassium Citrate, Vegetable Oil.

INDICATIONS AND USAGE

CORVITE® FE is indicated for the prevention and treatment of iron deficiency anemia and/or nutritional megaloblastic anemias.

CONTRAINDICATIONS

CORVITE® FE is contraindicated in patients with a known hypersensitivity to any of the components of this product. Hemochromatosis and hemosiderosis are contraindications to iron therapy.

WARNINGS

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} is deficient.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. KEEP THIS PRODUCT OUT OF THE 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 in doses above 1.0 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. Pernicious anemia should be excluded before using this product since folic acid may mask the symptoms of pernicious anemia.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Clinical studies on this product have not been performed in subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious.

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. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

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.

CLINICAL PHARMCOLOGY

Iron is an essential component in the formation of hemoglobin. Adequate amounts of iron are necessary for effective erythropoiesis. Iron also serves as a cofactor of several essential enzymes, including cytochromes that are involved in electron transport. Folic acid is required for nucleoprotein synthesis and the maintenance of normal erythropoiesis. Folic acid is converted in the liver and plasma to its metabolically active form, tetrahydrofolic acid, by dihydrofolate reductase. Vitamin B_{12} is required for the maintenance of normal erythropoiesis, nucleoprotein and myelin synthesis, cell reproduction and normal growth. Intrinsic factor, a glycoprotein secreted by the gastric mucosa, is required for active absorption of vitamin B_{12} from the gastrointestinal tract.

DOSAGE AND ADMINISTRATION

Usual adult dose is 1 tablet daily, or as prescribed by a physician.

HOW SUPPLIED

CORVITE® FE available in carton unit dose pack of 30 (6 child resistant blister cards of 5 tablets per card).
NDC 68025-042-30

STORAGE

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

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

Rx Only.

Manufactured for: Vertical Pharmaceuticals, Inc., Sayreville, NJ 08872

VERTICAL PHARMACEUTICALS, INC.

US Patent No. 5,516,925
US Patent No. 6,716,814
US Patent No. 7,838,042
US Patent No. 6,706,904
Other Patents Pending

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