

**INDICATIONS:** For the dietary management of individuals with anemia. Ferocon is labeled as a medical food intended for use under the active and ongoing medical supervision requiring medical care on a recurring basis for, among other things, instructions on the use of the medical food.

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

**Medical Foods:** Medical foods are intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modifications of a normal diet alone. Although a medical-food product is intended for use under the active and ongoing medical supervision, FDA does not require a prescription.

**These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

**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.**

If pregnant, or planning to become pregnant or are currently breast-feeding please contact your physician, or health-care provider before using or continuing use.

Lot #/Exp.:

1.7185"

51991-635-01

# Ferocon Capsules

## Hematinic Concentrate with Intrinsic Factor

Do not use this product if the inner safety seal under the cap is torn, broken or missing.

**WARNING: Cancer and Reproductive Harm - [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).**

Medical Food 100 Capsules

**breckenridge** A Towra Company

**Each Ferocon Capsule contains:**

Vitamin C (as Ascorbic Acid).....75 mg  
Folic Acid.....0.5 mg  
Vitamin B<sub>12</sub> (as Cyanocobalamin).....15 mcg  
Iron, elemental (as Ferrous Fumarate).....110 mg  
Liver Stomach Concentrate (Containing Intrinsic Factor).....240 mg

With other factors of Vitamin B Complex in the liver-stomach concentrate.

**Other ingredients:** Gelatin, Pharmaceutical Glaze, Dicalcium Phosphate, Magnesium Stearate, FD&C Red No. 40 Lake, Titanium Dioxide, FD&C Red No. 3 Lake, FD&C Green No. 3 Lake and FD&C Blue No. 1 Lake.

**HOW SUPPLIED:** Ferocon Capsules are scarlet/garnet, imprinted "B 635". Supplied in bottles of 100 capsules, 51991-635-01.

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature. Protect from light and moisture. Dispense in a tight, light-resistant container with a child-resistant closure as defined in the USP/NF.

To report a serious adverse event contact: 1-800-367-3395.

7752-05-20

**Manufactured by:**

Contract Pharmacal Corp.  
Hauppauge, NY 11788 USA

**Distributed by:**

Breckenridge Pharmaceutical, Inc.  
Berlin, CT 06037



PEEL HERE FOR MORE INFORMATION

**CONTRAINDICATIONS:** Hemochromatosis and hemosiderosis are contraindications to iron supplementation. This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

**WARNINGS:**

**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.**

Folic Acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B<sub>12</sub> is deficient.

As with all preparations containing intrinsic factor, resistance may develop in some cases of pernicious anemia to the potentiation of absorption of physiologic doses of vitamin B<sub>12</sub>. If resistance occurs, parenteral therapy or oral therapy with so-called massive doses of vitamin B<sub>12</sub> may be necessary for adequate treatment of the patient. No single regimen fits all cases, and the status of the patient observed in follow-up is the final criterion. Periodic clinical and laboratory tests are considered essential and are recommended.

**PRECAUTIONS**

**General:**

Folic acid, in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. Anemia is a manifestation that requires appropriate investigation to determine its cause or causes. Folic acid alone is unwarranted in the treatment of pure vitamin B<sub>12</sub> deficiency states, such as pernicious anemia.

**Pregnancy: Teratogenic Effects: Pregnancy Category C:**

Animal reproduction studies have not been conducted with this product. It is also not known whether this product can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This product should be given to a pregnant woman only if clearly needed.

**If pregnant, or planning to become pregnant or are currently breast-feeding please contact your physician, or health-care provider before using or continuing use.**

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in children below the age of 12, 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, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

**ADVERSE REACTIONS:** In rare instances, iron produces gastrointestinal reactions, such as diarrhea or constipation. Reducing the dose and administering it with meals will minimize these effects in the iron-sensitive patient.

In extremely rare instances, skin rash suggesting allergy has been noted following the oral administration of liver-stomach material. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

**DOSAGE AND ADMINISTRATION:** One capsule twice a day. (Two capsules daily produce a standard response in the average uncomplicated case of pernicious anemia). This product is not indicated for use in children under 12 years of age. (see **PRECAUTIONS, Pediatric Use.**)

**OVERDOSAGE**

**Symptoms:** Those of iron intoxication, which may include pallor and cyanosis, vomiting, hematemesis, diarrhea, melena, shock, drowsiness, and coma.

**Treatment:** For specific therapy, exchange transfusion and chelating agents. For general management, gastric and rectal lavage with sodium bicarbonate solution or milk, administration of intravenous fluids and electrolytes, and use of oxygen.