

TriHEMIC® 600

HEMATINIC TABLETS

DESCRIPTION

Each tablet contains: Vitamin C (Ascorbic Acid) 600 mg, Vitamin B₁₂ (Cyanocobalamin) 25 mcg, Intrinsic Factor Concentrate 75 mg, Folic Acid 1 mg, Vitamin E (d/-Alpha Tocopheryl Acetate) 30 Int. Units, Elemental Iron (as 350 mg of Ferrous Fumarate) 115 mg and Docusate Sodium USP (DSS) 50 mg.

Inactive Ingredients

Crospovidone, Hydroxypropyl Methylcellulose, Light Mineral Oil, Magnesium Stearate, Povidone, Red 40, Silicon Dioxide, Sodium Benzoate, Sodium Lauryl Sulfate and Titanium Dioxide.

ACTIONS

TriHEMIC 600 hematinic is a preparation containing those ingredients essential to normal erythropoiesis, plus a stool softener to counteract constipating effects of iron.

INDICATIONS

TriHEMIC 600 is a multiphasic preparation for use in the treatment of most megaloblastic, macrocytic and iron-deficiency anemias, in the anemias of pregnancy, in those anemias occurring in a variety of malabsorption syndromes, and those of nutritional origin. It is a useful adjuvant in patients in whom erythropoiesis is suppressed due to severe infections, malignancies or to the toxic effects of certain chemotherapeutic agents. A deficiency of Vitamin E may increase the fragility of red blood cells, with resultant enhanced hemolysis. Vitamin C is present to aid in the absorption of iron.

WARNINGS

Folic Acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B₁₂ is deficient.

PRECAUTIONS

Some patients affected with pernicious anemia may not respond to orally administered Vitamin B₁₂ with intrinsic factor concentrate and there is no known way to predict which patients will respond or which patients may cease to respond. Periodic examinations and laboratory studies of pernicious anemia patients are essential and recommended.

If any symptoms of intolerance occur, the drug should be temporarily or permanently discontinued.

Folic Acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive.

ADVERSE REACTIONS

Gastrointestinal intolerance may develop and be manifest by nausea, vomiting, diarrhea or abdominal pain. Skin rashes of various types may occur. Such reactions may necessitate temporary or permanent changes in dosage or usage.

Allergic sensitization has been reported following both oral and parenteral administration of Folic Acid.

DOSAGE AND ADMINISTRATION

One tablet daily. Adjustment of dosage is dependent on patient response and the physician's clinical judgment.

HOW SUPPLIED

TriHEMIC® 600 Tablets are oval-shaped, red, film coated, engraved T1 on one side and LL on the other are supplied as follows:

NDC 0005-4590-13 - Bottles of 30

NDC 0005-4590-31 - Bottles of 500

Store at controlled room temperature 15-30°C (59-86°F).

Caution: Federal law prohibits dispensing without prescription.



LEDERLE PHARMACEUTICAL DIVISION
of American Cyanamid Company, Pearl River, NY 10965