In vitro studies have shown that removal of iron dextran by dialysis is negligible.\(^1\)\(^,\)\(^2\) Six different dialyzer plasma by cells of the reticuloendothelial system, which split the complex into its components of iron and dextran. After intramuscular injection, iron dextran is absorbed from the injection site into the capillaries and the lymphatic system. Circulating iron dextran is removed from the plasma by cells of the reticuloendothelial system, which split the complex into its components of iron and dextran. The iron is immediately bound to the available protein moieties to form hemosiderin or ferritin, the physiological forms of iron, or to a lesser extent to transferrin. This iron which is subject to physiological control replenishes hemoglobin and depleted iron stores. Dextran, a poliglucose, is either metabolized or excreted. Negligible amounts of iron are lost via the urinary or alimentary pathways after administration of iron dextran. The major portion of intramuscular injections of iron dextran is absorbed within 72 hours; most of the remaining iron is absorbed over the ensuing 3 to 4 weeks. Various studies involving intravenously administered \(^{59}\)Fe iron dextran to iron deficient subjects, some of whom had coexisting diseases, have yielded half-life values ranging from 5 hours to more than 20 hours. The 5-hour value was determined for \(^{59}\)Fe iron dextran from a study that used laboratory methods to separate the circulating \(^{59}\)Fe iron dextran from the transferrin-bound \(^{59}\)Fe. The 20-hour value reflects a half-life determined by measuring total \(^{59}\)Fe, both circulating and bound. It should be understood that these half-life values do not represent clearance of iron from the body. Iron is not easily eliminated from the body and accumulation of iron can be toxic. In vitro studies have shown that removal of iron dextran by dialysis is negligible.\(^1\)\(^,\)\(^2\) Six different dialyzer membranes were investigated (polyisulfone, cuprophane, cellulose acetate, cellulose triacetate, poly-methylmethacrylate and polycyclohexilene), including those considered high efficiency and high flux.

**INDICATIONS AND USAGE:** Intravenous or intramuscular injections of iron dextran are indicated for treatment of patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible. **CONTRAINDICATIONS:** Hypersensitivity to the product. All anemias not associated with iron deficiency. **WARNINGS:** See BOXED WARNING. A risk of carcinogenesis may attend the intramuscular injection of iron-carbohydrate complexes. Such complexes have been found under experimental conditions to produce sarcoma when large doses or small doses injected repeatedly at the same site were given to rats, mice, and rabbits, and possibly in hamsters. The long latency period between the injection of a potential carcinogen and the appearance of a tumor makes it impossible to measure accurately the risk in man. There have, however, been several reports in the literature describing tumors at the injection site in humans who had previously received intramuscular injections of iron-carbohydrate complexes. Large intravenous doses, such as used with total dose infusions (TDI), have been associated with an increased incidence of adverse effects. The adverse effects frequently are delayed (1-2 days) reactions typified by one or more of the following symptoms: arthralgia, backache, chills, dizziness, moderate to high fever, headache, malaise, myalgia, nausea, and vomiting. The onset is usually 24-48 hours after administration and symptoms generally subside within 3-4 days. These symptoms have also been reported following intramuscular injection and generally subside within 3-7 days. The etiology of these reactions is not known. The potential for a delayed reaction must be considered when estimating the risk/benefit of treatment. The maximum daily dose should not exceed 2 mL undiluted iron dextran. This preparation should be used with extreme care in patients with serious impairment of liver function. It should not be used during the acute phase of infectious kidney disease. Adverse reactions experienced following administration of INFeD may exaggerate cardiovascular complications in patients with preexisting cardiovascular disease. **PRECAUTIONS:** General: Unwarranted therapy with parenteral iron will cause excessive storage of iron with the consequent possibility of exogenous hemosiderosis. Such iron overload is particularly apt to occur in patients with hemolytic anemias and other refractory anemias that might be erroneously diagnosed as iron deficiency anemias. INFeD should be used with caution in individuals with histories of significant allergies and/or asthma. Anaphylaxis and other hypersensitivity reactions have been reported after uneventful test doses as well as therapeutic doses of iron dextran injection. Therefore, administration of subsequent test doses during therapy should be preceded by an adequate period of observation. (See DOSAGE AND ADMINISTRATION: Administration.) Epinephrine should be immediately available in the event of hyperacute hypersensitivity reactions. (Usual adult dose: 0.5 mL of a 1:1000 solution, by subcutaneous or intramuscular injection.) Note: Patients using beta-blocking agents may not respond adequately to epinephrine. Isoproterenol or similar beta-agonist agents may be required in these patients. Patients with rheumatoid arthritis may have an acute exacerbation of joint pain and swelling following the administration of INFeD. Reports in the literature from countries outside the United States (in particular, New Zealand) have suggested that the use of intramuscular iron dextran in neonates has been associated with an increased incidence of gram-negative sepsis, primarily due to E. Coli.
Based on: Desired Hb = the target Hb in g/dl.

mated as follows:

The total amount of INFeD in mL required to treat the anemia and replenish iron stores may be approxi-

Table values were calculated based on a normal adult hemoglobin of 14.8 g/dl for weights greater than

LBW = Lean body weight in kg. A patient's lean body weight (or actual body weight if less than lean

For females: LBW = 45.5 kg + 2.3 kg for each inch of patient's height over 5 feet

To calculate a patient's weight in kg when lbs are known:

W = Weight in kg.

Based on: Desired Hb = the target Hb in g/dl.

Normal Hb for Children 15 kg or less is 12 g/dl

Dose (mL) = 0.0442 (Desired Hb - Observed Hb) x W + (0.26 x W)

Alternatively the total dose may be calculated:

Dose (mL) = 0.0442 (Desired Hb - Observed Hb) x W + (0.26 x W)

Based on: Desired Hb = the target Hb in g/dl.

Normal Hb for Children 15 kg or less is 12 g/dl

W = Weight in kg.

To calculate a patient's weight in kg when lbs are known:

Children 5 - 15 kg (11 - 33 lbs): See Dosage Table.

INFeD should not normally be given in the first four months of life. (See PRECAUTIONS: Pediatric Use)

Alternatively the total dose may be calculated:

Dose (mL) = 0.0442 (Desired Hb - Observed Hb) x W + (0.26 x W)

Based on: Desired Hb = the target Hb in g/dl.

Normal Hb for Children 15 kg or less is 12 g/dl

W = Weight in kg.

To calculate a patient's weight in kg when lbs are known:

patient's weight in pounds = weight in kilograms

2.2