FIORE

COMPOSITION:

Each ml contains:
Elemental Iron as Iron Sucrose (M.S).....20mg
Product conforms to U.S.P Specifications.

DESCRIPTION:

Fiore injection is an aqueous complex of
Elemental Iron with Sucrose.

CLINIICAL PHARMACOLOGY:

Mechanism of Action
Iron Sucrose (Fire) is a complex of Elemental Iron and Sucrose. Following intravenous administration, Iron Sucrose (Fiore) is dissociated into
-Iron and Sucrose and the Iron is transported as a complex with transferrin to target cells including erythroid precursor cells. The iron in the
precursor cells is incorporated into hemoglobin as the cells mature into red blood cells.
Pharmacokinetics
In healthy adults treated with intravenous doses of Iron Sucrose (Fiore), its Iron component exhibited first-order kinetics:
Elimination half life (*,,) 6 hours
Total clearance 1.2 Liters per hour
Non Steady State apparent volume of distribution 10.0 Liters
Steady state apparent volume of distribution 7.9 Liters
Since Iron disappearance from the serum depends on the need for Iron in the Iron stores and Iron utilizing tissues of the body, serum clearance
of Iron is expected to be more rapid in Iron deficient patients treated with Iron Sucrose (Fire) as compared with healthy individuals
Distribution:
In healthy adults, the Iron component of Iron Sucrose appears to distribute mainly in the blood and to some extent in extravascular fluid
Metabolism:
Iron sucrose is dissociated into Iron and Sucrose by the reticuloendothelial system.
Elimination:
The Sucrose component is eliminated mainly by urinary excretion. Some Iron is also eliminated in the urine (approximately 5%).

INDICATIONS:

Iron Sucrose (Fiore) is indicated in:
• Iron deficiency anemia in patients on chronic hemodialysis and who have received supplemental Erythropoietin therapy.
• Iron deficiency because of other reasons e.g. before and after surgery, final stages of pregnancy, intolerance, non-responsiveness or non-
compliance to oral Iron therapy malabsorption etc.

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DOSAGE AND ADMINISTRATION:

Dosage:
Normal dosage:
Adults and Elderly:
5 - 10ml (100 to 200 mg Iron) once to three times a week depending on the hemoglobin level.
Children:
There is limited data on children under study conditions. If there is a clinical need, it is recommended not to exceed 0,15ml (=3mg Iron/kg
body weight) once to three times a week depending on the hemoglobin level.
Maximum tolerated single dose:
Adults and Elderly:
As Injection: 10ml (200mg Iron) Injection in at least 10 minutes
As infusion: When the clinical situation demanded, doses up to 500 mg have been administered.
The maximum tolerated single dose is 7mg Iron per kg body weight given once per week but not exceeding 500mg Iron
Administration:
Iron Sucrose (Fiore) is exclusively to be administered intravenously by drip infusion. Before administration a test dose should be administered.
If any allergic reaction or intolerance occurs during administration, therapy must be stopped immediately.
Iron Sucrose (Fiore) may preferably be administered by drip infusion (in order to reduce the risk of hypotensive episodes). 1ml (20mg Iron) has
to be diluted exclusively in max. 20ml of 0,99 w/v Sodium Chloride solution, immediately prior to infusion (i.e. 5ml in max 100ml 0.9% w/v
Sodium Chloride solution up to 25ml in max. 500 ml 0,9% w/vSodium Chloride solution). The solution should be infused at a rate of:
100ml in at least 15min
200ml in at least 30min
300ml in at least 1.5h
400ml in at least 2.5h
500ml in at least 3.5h

CONTRAINDICATIONS:

The use of Iron Sucrose (Fiore) is contraindicated in cases of:
• Anemia not attributable to Iron deficiency
• Iron overload or disturbances in utilization of Iron
• A history of hypersensitivity to parenteral Iron preparations
• Patients with a history of asthma, eczema or other atopic allergy, because they are more susceptible to experience allergic reactions
• History of cirrhosis or hepatitis or the presence of serum transaminases greater than three times the upper limit of normal values
• First trimester of pregnancy

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WARNINGS:

Iron sucrose should only be administered where the indication is confirmed by appropriate investigations (e.g. serum ferritin, hemoglobin
(Hb), hematocrit, erythrocyte count, red cell indices-MCV, MCH and MCHC)
Parenterally administered iron preparations can cause allergic or anaphylactoid reactions. In the case of a mild allergic reaction, antihistamines
should be administered; in the case of a serious anaphylactoid reaction adrenaline should be administered immediately, Patients with
bronchial asthma, with low iron binding capacity and / or folic acid deficiency are particularly at risk of an allergic or anaphylactoid reaction.
Iron sucrose must be used with care in patients with serious hepatic dysfunction. Hypotensive episodes may occur if injection is administered
too rapidly.

PRECAUTIONS:

Avoid freezing and Injection should not be used if container is leaking, solution is cloudy or it contains undissolved particles,
Iron Sucrose (Fiore) must only be mixed with 0,99% w/v NaCl solution. No other intravenc dilution solutions and therapeutic agent should
be used as there is a potential for precipitation and/or interaction.

USE IN PREGNANCY & LACTATION:

Pregnancy;
Pregnancy Category B;Reproductive toxicity studies in animals have shown that iron sucrose is not teratogenic or empryocidal in
non-anemic pregnant animals. However the use of parenteral iron preparations during the first three months has to be discouraged. During
the second and third term the application has to be done with caution.
Lactation:
Iron Sucrose is excreted in milk of rats. 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 Iron Sucrose Complex is administered to a nursing mothers.

DRUG-DRUG INTERACTIONS:

As with all parenteral Iron preparation, Iron Sucrose (Fire) should not be administered concomitantly with oral Iron preparations since the
absorption of oral Iron is reduced. Therefore an oral Iron therapy should at least be started 5 days after the last injection

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ADVERSE DRUG REACTIONS:

Serious side effects may include:
- Chest pain
- Swelling in hands, ankles or feet
- Trouble breathing
- Dangerously high blood pressure (severe headache, blurred vision, buzzing in ears, anxiety, confusion, chest pain, shortness of breath,uneven heartbeats and seizure).

Less serious side effects may include;
- Muscle cramps
- Weakness, tired feeling
- Dizziness, anxiety, headache
- Nausea, vomiting, stomach pain
- Diarrhea, constipation
- Ear pain
- Sore throat, sinus pain or congestion
- Decreased sense of taste
- Joint pain
- Pain, swelling, burning or irritation around the IV needle

OVER DOSAGE:

Excessive dosages of Iron Sucrose (Fire) may lead to accumulation of iron in storage sites potentially leading to hemosiderosis. Do not administer Iron Sucrose (Fiore) to patients with iron overload

INSTRUCTIONS:

Store in a cool & dry place below 25°C.
Protect from heat, light and moisture.
Keep out of reach of children.

PRESENTATION:

Fiore Injection is available in a blister Pack of 5 × 5ml ampoule
Fiore Injection is available in a blister Pack of 1 × 5ml ampoule (Physician Sample)