Megafer Injection

(Iron Sucrose)

COMPOSITION:
Each 5ml ampoule contains:
Iron Sucrose equivalent to Elemental Iron ... 100mg. [USP Specs.]

Excipients: Sodium Hydroxide, Water for Injection.

DESCRIPTION: Megafer (Iron Sucrose) Injection is a brown, sterile, aqueous complex of iron (III) hydroxide in sucrose, containing 20mg elemental iron per ml.
Molecular Formula: $[Na_2Fe_5O_8(OH)\cdot 3(H_2O)]_n\cdot m(C_{12}H_{22}O_{11})$
Molecular Weight: Approximately 34,000-60,000 daltons.

PHARMACODYNAMICS/MECHANISM OF ACTION: Following intravenous administration, Iron Sucrose is dissociated into iron and sucrose by the reticuloendothelial system and iron is transferred from the blood to a pool of iron in the liver and bone marrow. Ferritin, an iron storage protein, binds and sequesters iron in a non-toxic form, from which iron is easily available. Iron binds to plasma transferrin, which carries iron within the plasma and the extracellular fluid to supply the tissues. The transferrin receptor, located in the cell, and the transferrin-receptor complex is returned to the cell membrane. Transferrin without iron (apotransferrin) is then released to the plasma. The intracellular iron becomes (mostly) hemoglobin in circulating red blood cells (RBCs). Transferrin synthesis is increased and ferritin production reduced in iron deficiency. The converse is true when iron is plentiful.

PHARMACOKINETICS: Volume of distribution (V_{dss}) in healthy adults is 7.9L. Iron component has an elimination half life of 6 hours. Serum clearance of iron is faster in patients who are suffering from iron deficiency as compared to healthy individuals. Only 5% of iron is excreted via urine.

INDICATIONS: Iron deficiency anemia in patients on chronic hemodialysis and who have received supplemental erythropoietin therapy. Iron deficiency because of other reason/s e.g. before and after surgery, final stages of pregnancy, intolerance, non-responsiveness or non-compliance to oral iron therapy, malabsorption etc.

DOSAGE AND ADMINISTRATION: Recommended Dosage: 100mg iron 1-3 times/week depending on the hemoglobin level. The total treatment regimen is of 1,000mg in 10 doses. If required, the treatment can be repeated. **Megafer** Injection is to be administered intravenously only either by slow injection or by infusion.

CONTRA-INDICATIONS: Megafer Injection is contra-indicated in iron overload, known hypersensitivity to Iron Sucrose or any of its ingredients and non-iron deficiency anemias.

PRECAUTIONS: Since excretion of iron is very little and extra iron is accumulated in tissues causing undue effects, **Megafer** Injection should not be administered in patients with tissue iron overload. In such patients hematologic and hematinic monitoring should be exercised periodically e.g. hemoglobin, hematocrit, serum ferritin and transferrin saturation before starting therapy with **Megafer** Injection.

SIDE EFFECTS: There are reports of hypotension occurring in hemodialysis patients receiving intravenous iron. Other possible side effects are headache, vomiting, nausea, dizziness, joint aches, paresthesia, abdominal and muscle pain, edema, and cardiovascular collapse particularly in cases when Iron Sucrose Injection is administered in higher doses or rapidly.

USE IN PREGNANCY: Pregnancy Category B: Animal studies have not shown any evidence of impaired fertility or fetal harm following IV administration of Iron Sucrose. However, there is insufficient data in pregnant women to confirm this finding. Since human response can not be predicted on the basis of animal studies, **Megafer** Injection should be used during pregnancy only when benefits outweigh risks.

USE IN NURSING MOTHERS: Though in animal studies iron has been found to be excreted in milk, it is not known if it is excreted in human milk as well. Since drugs are excreted in human milk in general, **Megafer** Injection should be administered with caution in nursing mothers.

USE IN CHILDREN: There is insufficient data to establish the efficacy and safety of **Megafer** Injection in children.

USE IN OLD AGE: There is insufficient data to confirm any difference in the efficacy and safety of **Megafer** Injection in geriatric patients as compared with younger individuals.

OVERDOSAGE: Overdosage of **Megafer** Injection i.e. over and above the iron requirement might cause hemosiderosis. Symptoms associated with overdosage or rapid Iron Sucrose administration might lead to hypotension, headache, vomiting,

Rev: 07-13/2

nausea, dizziness, joint aches, paresthesia, abdominal and muscle pain, edema, and cardiovascular collapse. In such cases corrective and supportive measures should be instituted like IV fluids, hydrocortisone, and/or antihistamines.

DRUG INTERACTIONS: Megafer Injection should not be co-administered with oral iron preparations.

DIRECTIONS FOR USAGE: Do not administer if sediments are observed during the visual examination of injection. The injections, which are free from sediments and have homogeneous solution, are to be used.

OPEN CONTAINER SHELF LIFE: The product is to be used at once to avoid the microbial contamination.

0.9% Sodium Chloride Diluted Product Shelf Life: At room temperature, **Megafer** Injection diluted with 0.9% NaCl solution is physically and chemically stable for 12 hours (in-use stability). Diluted **Megafer** Injection should be immediately used to avoid bacterial contamination. If diluted **Megafer** Injection is not used immediately, its in-use storage time & prior conditions will totally be the responsibility of the user. It would however not be more than 3 hours at room temperature.

INSTRUCTIONS: Store below 30°C. Do not freeze. Protect from light. Keep out of the reach of children.

PRESENTATION: Megafer Injection 100mg/5ml is available in pack of 5 ampoules.

میگافر انجکشن

(آئرن سکروز)

اجزائے ترکیب: ہر ۵ ملی لیٹر ایمپیول میں آئرن سکروز ۱۰۰ ملی گرام عنصر فولاد کے برابر موجود ہے۔

بیان: میگافر انجکشن محلول کی صورت میں صرف بذریعہ وریدی ہی مریض کو دیا جاتا ہے۔ جب میگافر انجکشن بذریعہ وریدی مریض کو لگایا جاتا ہے تو یہ رٹیکولو اینڈوتھیلیل نظام کے تحت فولاد اور سکروز میں تحلیل ہو جاتا ہے۔

علامات: میگافر انجکشن مندرجہ ذیل علامات میں تجویز کیا جا سکتا ہے۔ طبی ضرورت کے تحت جب سرعت فولاد کا مہیا کرنا ہو۔ آنتوں کی سوزش کے مرض میں جب منہ کے ذریعے استعمال کی جانے والی فولاد کی دوا غیر مؤثر ہو۔ حمل کے آخری مراحل میں فولاد کی کمی میں جب منہ کے ذریعے استعمال کی جانے والی فولاد کی دوا غیر مؤثر ہو، فولاد کا کم جذب ہونا، عمل جراحت سے پہلے اور بعد وغیرہ۔ میگافر انجکشن گردوں کے مریضوں میں فولاد کی کمی سے ہونے والے انیمیا میں بھی دیا جاتا ہے۔

خوراک اور طریقہ استعمال: میگافر انجکشن صرف بذریعہ وریدست روی سے یا انفیوژن کے طریقہ سے مریض کو لگایا جائے۔

بالغ افراد کیلئے: میگافر انجکشن کی خوراک مریض کے ہیموگلوبن لیول پر منحصر ہوتی ہے۔ میگافر انجکشن ۵ ملی لیٹر (۱۰۰ ملی گرام) ہفتے میں اسے ۳ مرتبہ دیا جاتا ہے۔ مکمل خوراک ۱۰۰۰ ملی گرام ہے جو کہ ۱۰ خوراکوں پر منحصر ہے میگافر انجکشن کے علاج کو بوقتِ ضرورت دہرایا جا سکتا ہے۔

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ منجمد ہونے سے بچائیں۔ روشنی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

طریقہ فراہمی: میگافر انجکشن ۵ ملی لیٹر ۵ ایمپیولز کے پیک میں دستیاب ہیں۔

Manufactured by:
Surge Laboratories (Pvt.) Ltd.,
10th Km, Faisalabad Road, Bikhi,
District Sheikhupura Pakistan.

Rev: 07-13/2