For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

IRON SUCROSE INJECTION USP

SUCRONIR™*

STERILE SOLUTION FOR I.V. USE

DESCRIPTION:
SUCRONIR™* is a brown, aqueous, complex of polynuclear iron (III)-hydroxide in sucrose for intravenous use, having a molecular weight of approximately 34,000-60,000 Daltons.

COMPOSITION:
Each ml contains:

Ferric Hydroxide in complex with Sucrose	
Eq. to Elemental Iron	20 mg
Water for Injections IP	q. s.

Osmolarity Approx.: 1250 mOsmol/L

PHARMACODYNAMICS:
Following intravenous administration, iron sucrose is dissociated by the reticuloendothelial system into iron and sucrose. In 22 haemodialysis patients on erythropoietin therapy treated with iron sucrose containing 100 mg of Iron, three times weekly for three weeks, significant increases in serum iron and serum ferritin and significant decreases in total iron binding capacity occurred four weeks from the initiation of iron sucrose treatment.

PHARMACOKINETICS:
In healthy adults iron component of iron sucrose exhibits first order kinetics with an elimination half-life of 6 hrs with total clearance of 1.2 L/h. Serum clearance of iron is expected to be more rapid in iron deficient patients as compared to healthy individuals. Significant amount of the administered iron distributes in the liver, spleen and bone marrow and the bone marrow is an iron trapping compartment and not a reversible volume of distribution. The sucrose component is eliminated mainly by urinary excretion. Some iron (5%) also is eliminated in the urine.

INDICATIONS:
Treatment of iron deficiency anaeamia in patients with chronic renal failure or those undergoing chronic haemodialysis receiving supplemental erythropoietin therapy.

CONTRAINDICATIONS:
The use of SUCRONIR™* is contraindicated in patients with evidence of iron overload, in patients with known hypersensitivity to SUCRONIR™* or any of its inactive components, and in patients with aneamia not caused by iron deficiency.

PRECAUTIONS:
Because body iron excretion is limited and excess tissue iron can be hazardous, caution should be exercised to withhold iron administration in the presence of evidence of tissue iron overload. Patients receiving SUCRONIR™* require periodic monitoring of haematologic and haematinic parameters (haemoglobin, haematocrit, serum ferritin and transferrin saturation). Iron Therapy should be with held in patients with evidence of iron overload. Transfarrin saturation values increase repidly after IV administration of Iron Therapy should be with held in patients with evidence of iron sucrose; thus serum iron values may be reliably obtained 48 hours after IV dosing.

DRUG INTERACTIONS:
Like other parenteral iron preparations, SUCRONIR™* may be expected to reduce the absorption of concomitantly administered oral iron preparations….

USE IN PREGNANCY AND LACTATION:
Pregnancy Category B: Teratology studies have been performed in rats and rabbits and have revealed no evidence of impaired fertility or harm to the foetus. There are, however, no adequate and well controlled studies in pregnant women. SUCRONIR™* injection should be used during pregnancy only if clearly needed. Because many drugs are excreted in human milk, caution should be exercised when SUCRONIR™* is administered to a nursing woman.

PAEDIATRIC USE:
Safety and effectiveness of SUCRONIR™* in patients have not been established.

GERIATRIC USE:
Reported clinical experience has not identified differences in responses between the elderly and younger patients. However, 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:
The safety of iron sucrose has been documented in chronic renal failure patients exposed to single doses of 100 mg iron IV as iron sucrose given up to three times weekly for up to ten doses. Adverse events, whether or not related to iron sucrose administration, reported by treated patients are as follows: hypotension, cramps/leg cramps, nausea, headache, vomiting, diarrhea and hypersensitivity reactions.

OVERDOSAGE:
Dosages of iron sucrose in excess of iron needs may led to accumulation of iron in storage sites leading to haemosiderosis. Periodic monitoring of iron parameters such as serum ferritin and transferritin saturation may assist in recognizing iron accumulation. SUCRONIR™* should be administered to patients with iron overload and should be discontinued when serum ferritin levels equal or exceed established guidelines. Symptoms associated with over dosage or infusing SUCRONIR™* too rapidly included hypotension, headache, vomiting, nausea, dizziness, joint aches, paresthesia, abdominal and muscle pain oedema, and cardiovascular collapse. Most symptoms have been successfully treated with IV fluids, hydrocortisone, and/or antihistamines. Infusing the solution as recommended or at a slower rate may also alleviate symptoms.

DOSAGE AND ADMINISTRATION:

Adults: 100 mg iron administered one to three times per week to a total dose of 1000 mg in 10 doses. Repeat if needed. Frequency of dosing should be no more than three times weekly. The recommended dosage of SUCRONIR™* for the repletion treatment of iron deficiency in haemodialysis patients can be delivered intravenously (directly into the dialysis line) during the dialysis session. Patients may continue to require therapy with SUCRONIR™* at the lowest dose necessary to maintain target levels of haemoglobin, haematocrit and laboratory parameters of iron storage within acceptable limits.

Slow Intravenous injection: SUCRONIR™* may be administered by slow intravenous injection at a rate of 1 ml (20 mg iron) undiluted solution per minute [i.e., 5 minutes per ampoule] not exceeding one ampoule SUCRONIR™* [100 mg iron] per injection. Discard any unused portion.

Infusion: SUCRONIR™* may also be administered by intravenous infusion. This may reduce the risk of hypotensive episodes. The content of each ampoule must be diluted exclusively in a maximum of 100 ml of 0.9 % NaCl, immediately prior to infusion. The solution should be infused at a rate of
100 mg of iron over a period of at least 15 minutes. Unused diluted solution should be discarded.

NOTE: Do not mix SUCRONIR™* with other medications or add to parenteral nutrition solutions for intravenous infusion. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit.

STORAGE:

Store in cool, dry & dark place.

PRESENTATION:

SUCRONIR™* Injection is available in 5 mL glass ampoule in a PVC Tray packed in a mono carton.

aculife®

Manufactured in India by:
Aculife Healthcare Pvt. Ltd.
Sachana, Gujarat 382150, India.

* TM owners-Nirma Ltd.