Rx Iron Sucrose Encifer®

20 mg / mL
Solution for Injection (IV)
Hematinic

COMPOSITION
Encifer®
Each mL contains:
Ferric Hydroxide in Complex with Sucrose equivalent to elemental Iron...20 mg

List of Excipients : Sodium Hydroxide BP, Water for injection BP

DESCRIPTION
Encifer is a brown, sterile, aqueous complex of polynuclear iron (III)-hydroxide in sucrose (Iron Sucrose) for intravenous use. Iron sucrose injection has a molecular weight of approximately 34,000 - 60,000 daltons.

Each ml contains 20 mg elemental iron as iron sucrose in water for injection. Iron sucrose is available in 5ml single dose ampoule (100 mg elemental iron per 5 ml). The product contains approximately 30% sucrose w/v (300 mg/mL) and has a pH of 10.5-11.1 at 20ºC. The product contains no preservatives. The osmolarity is not less than 1150 and not more than 1350 mOsmol/L.

CLINICAL PHARMACOLOGY
Pharmacodynamics: Following intravenous administration, iron sucrose is dissociated by the reticuloendothelial system into iron and sucrose.
Pharmacokinetics: Following intravenous doses of Iron sucrose, the iron component exhibits first order kinetics with an elimination half-life of 6 h, total clearance of 1.2 L/h, non-steady state apparent volume of distribution of 10.0 L and steady state apparent volume of distribution of 7.9 L. Since iron disappearance from 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 as compared to healthy individuals. The effects of age and gender on the pharmacokinetics of Iron sucrose have not been studied.
Distribution: Following intravenous administration of Iron sucrose, the iron component appears to distribute mainly in blood and to some extent in extravascular fluid. Significant amount of administered iron is distributed in the liver, spleen and bone marrow.
Metabolism and Elimination: Following intravenous administration, Iron sucrose dissociated into iron and sucrose by the reticuloendothelial system. The sucrose component is eliminated mainly by urinary excretion.

INDICATIONS AND USAGE
Treatment of Iron Deficiency Anemia in the following patients:

1. Hemodialysis Dependent Chronic Kidney Disease (HDD-CKD) patients receiving an Erythropoietin.
2. Peritoneal Dialysis Dependent Chronic Kidney Disease (PDD-CKD) patients receiving an Erythropoietin.
3. Non-Dialysis Dependent Chronic Kidney Disease (NDD-CKD) patients receiving or not receiving an Erythropoietin.
4. During Pregnancy and Post partum.

DOSAGE & ADMINISTRATION
The dosage of Iron sucrose is expressed in terms of mg of elemental iron. Each ml contains 20 mg of elemental iron.

Administration: Iron sucrose must only be administered intravenously either by slow injection or by infusion.

Hemodialysis Dependent Chronic Kidney Disease Patients (HDD-CKD):
The recommended dose of Iron sucrose is 100mg (5ml) administered one to three times per week; most patients will require a minimum cumulative dose of 1000mg over 10 sequential dialysis sessions. Patients may continue to require therapy with Iron sucrose at the lowest dose necessary to maintain target levels of hemoglobin, hematocrit and laboratory parameters of iron storage within acceptable limits. Iron sucrose can be administered as slow intravenous injection or as an intravenous infusion.
Slow Intravenous Injection: Iron Sucrose may be administered undiluted by slow intravenous injection into the dialysis line over 2 to 5 minutes.
Infusion: Iron Sucrose may be administered by infusion (into the dialysis line for hemodialysis patients) as every 5 ml Iron Sucrose diluted exclusively in a maximum of 100 ml of 0.9% NaCl, immediately prior to infusion. The solution must be infused at a rate of 100 mg of iron over a period of at least 15 minutes. Unused diluted solution must be discarded.

Non-Dialysis Dependent Chronic Kidney Disease Patients (NDD-CKD):
Iron Sucrose is administered as a total cumulative dose of 1,000 mg over a 14 day period as a 200 mg slow IV injection undiluted over 2 to 5 minutes on 5 different occasions within the 14 day period. There is limited experience with administration of an infusion of 500 mg of Iron Sucrose, diluted in a maximum of 250 mL of 0.9% NaCl, over a period of 3.5-4 hours on day 1 and day 14.

Peritoneal Dialysis Dependent Chronic Kidney Disease Patients (PDD-CKD):
Iron sucrose is infused intravenously in three divided doses for a total dose of 1000 mg during a 28-day period: two infusions of 300 mg over 1.5 hours 14 days apart, followed by one 400-mg infusion over 2.5 hours 14 days later.

NOTE: Do not mix Encifer 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.

Anemia during Pregnancy and Post-Partum
The total required of Iron should be administered as 100 to 200 mg iron sucrose as a single dose repeated three times a week. The amount of Iron required can be calculated using:

Anemia during Pregnancy
Total Iron Dose (mg) = 2.4 x W x d + 500
W= Weight Before Pregnancy in Kg
d= (Target Hb – Actual Hb) in gm/dl

Post-partum anemia
Total Iron Dose (mg) = 2.4 x W x d
W= Body Weight n Kg
d= (Target Hb-Actual Hb) in gm/dl

Iron Sucrose is administered by **Slow Intravenous Injection:** At the rate of 1mL (20mg Iron) solution per minute not exceeding 100 mg Iron per injection. Unused solution must be discarded. **Infusion:** Every 2.5ml diluted exclusively in a maximum of 100ml of 0.9% NaCl, immediately prior to infusion. The solution must be infused at a rate of 100mg/15 minutes. Unused diluted solution must be discarded.

SIDE EFFECTS
Side effects include hypotension, chest pain, hypertension, hypervolemia, CHF, cramps, musculoskeletal pain, diarrhea, nausea, vomiting, abdominal pain, elevated liver enzymes, skin irritation, pruritis, application site reaction, dizziness, dyspnea, pneumonia, cough, headache, fever, asthenia, malaise.

DRUG INTERACTIONS
Iron sucrose should not be administered concomitantly with oral iron preparations since the absorption of oral iron is reduced.

WARNINGS
Hypersensitivity reactions have been reported with injectable iron products.

PRECAUTIONS
General: 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 Iron sucrose requires periodic monitoring of hematologic and hematinic parameters. Iron therapy should be withheld in patients with evidence of iron overload. Transferrin saturation values increase rapidly after IV administration of iron sucrose; thus, serum iron values may be reliably obtained 48 hours after IV dosing.
Hypersensitivity Reactions: Serious hypersensitivity reactions have been rarely reported in patients receiving Iron sucrose.
Hypotension: Hypotension has been reported in chronic kidney disease patients receiving intravenous iron. Hypotension following administration of Iron sucrose may be related to rate of administration and total dose administered. Caution should be taken to administer Iron sucrose according to recommended guidelines.
Carcinogenesis, Mutagenesis, and Impairment of Fertility: No long-term studies in animals have been performed to evaluate the carcinogenic potential of Iron sucrose.
Pregnancy Category B: No adequate and well controlled studies in pregnant women have been reported. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.
Nursing Mothers: 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 is administered to a nursing woman.
Pediatric Use: Safety and effectiveness of Iron sucrose in pediatric patients have not been established.
Geriatric Use: There are no identified differences in responses between elderly and younger patients, but greater sensitivity of some of the older individuals cannot be ruled out.

OVERDOSE AND TREATMENT
Dosages of Iron sucrose in excess of iron needs may lead to accumulation of iron in storage sites leading to hemosiderosis. Periodic monitoring of iron parameters such as serum ferritin and transferrin saturation may assist in recognizing iron accumulation. Iron sucrose should not be administered to patients with iron overload and should be discontinued when serum ferritin levels equal or exceed established guidelines. Particular caution should be exercised to avoid iron overload where anemia unresponsive to treatment has been incorrectly diagnosed as iron deficiency anemia.
Symptoms associated with overdosage or infusing Iron sucrose too rapidly included hypotension, dyspnoea, headache, vomiting, nausea, dizziness, joint aches, paresthesia, abdominal and muscle pain, edema, 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.
For suspected adverse drug reaction,report to FDA: www.fda.gov.ph seek medical attention immediately at first sign of adverse drug reaction.

CONTRAINDICATIONS
The use of Iron sucrose is contraindicated in patients with evidence of iron overload, in patients with known hypersensitivity to it or any of its inactive components, and in patients with anemia not caused by iron deficiency.

CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION
Store at temperature not exceeding 30°C. Do not freeze.

AVAILABILITY : 5 mL USP Type I Transparent Flint Glass Ampule (Box of 5's)

FDA REG. No.: DR-XY33701
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Emcure
PHARMACEUTICALS LTD.
Hinjawadi, Pune - 411 057, INDIA.
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Product	Encifer	**New / Revised A/W**	Revised A/W	**FDA Lic. Availability**	Awaited
Dosage form	Injection	**Reason for change**	Editorial changes	**Proof 1**	09.07.2019
Therapeutic Category	Haematinics	**Colour Scheme**	Black	**Corrections of Proof 1**	Editorial changes
Item	Philippine Export Pack Insert A/W	**Pantone Shades**	N.A.	**Proof 2**	11.07.2019
Dimension	L. 80 x H. 210 mm (Folded 80 x 27 mm)	**Total No. of Colours**	1	**Corrections of Proof 2**	Editorial changes
Substrate	Super white maplitho paper (J. K. Mill)	**Special Effect (if any)**	N.A.	**Proof 3**	15.07.2019
Specification	60 GSM	**Item Code**	510009824PH02	**Corrections of Proof 3**	
Printing Area	B/B	**Marketing Division**	Emcure Export	**Final**	
Item Style	N.A.	**Design / Colour Approved on**	N.A.	**A/W Checked by**	PMD Cell
A/W Proportion	Same Size	**Vendor**		**A/W Verified by**	Production / QC
Product Status	Emcure L/L Samrudh	**Country**	Philippine	**A/W Approved by**	Unit Head
Remark (If any) : Change in Text as per country guidelines.					

Proof 4	29.07.2022
Proof 5	03.08.2022
Proof 6	04.08.2022
Proof 7	09.08.2022