100 mg/5 mL Solution for Injection (I.V.)

(Single-Dose Only)

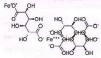
Anti-anemia FORMUL ATION-

Each 5 mL contains Ferric hydroxide in complex with sucrose equivalent to 100 mg ... 100 mg

PRODUCT DESCRIPTION:

Traductor Jessen Truot:

In Success highering a startle, dark brown slightly viscous solution of terric hydroxide in complex with Sucrose in Water
for fingledon filled in a Smit Lamber coloured glass ampoale centaining Ferric hydroxide in complex with Sucrose as its
active ingredient. Its chemical name is (28,3,4,5,56,6)-2 ((28,3,4,5,6))-4,-4((bydroxy,6-2-b))
bichydroxynethylydoxaba-y-jloys-6/ghydroxynethylydoxaera-y-jloys-6/ghydroxynethyloxaera-y-jloys-6/ghydroxynethyloxaera-y-lioys-6-ghydroxynethyl-y-lioys-6-ghydroxynethyl-y-lioys-6-ghydroxynethyl-y-



THERAPEUTIC CLASSIFICATION:

PHARMACODYNAMIC PROPERTIES.

Following intravenous administration of Iron Sucrose Injection, iron sucrose is dissociated by the reticuloendothelial system fino iron and sucross. In 22 hemodialysis patients on crythropoletin (recombinant human crythropoletin) therapy retaated with iron sucrose containing 100 mg of iron, three times weekly for three weeks, significant increases in serum iron and serum lernita and significant decreases in total iron binding capacity occurred four weeks from the initiation of iron sucrose treatment.

PHARMACOKINETIC PROPERTIES:

PHARMMOCKINETIC PROPERTIES:
Following intravensus lipication of a single dose of Iron sucrose Injection containing 100 mg Iron in healthy volunteers, maximum Iron levels, averaging 539 µmolt, were obtained 10 minutes after injection. The volume of distribution of the central compartment corresponded with the volume of joining and proprimately 3 fitters).

The Iron lipicated was rapidly cleared from the plasma, the terminal half-life being approximately 6 h. The volume of distribution ast dearly state was about alliers, indicating and view roll adolf being in the body field. Que to the lower scalability of iron sucrose in comparison to transferrin, a competitive exchange of Iron to transferrin was observed. This resulted in Iron transport of approximately 31 mg iron/24 h.

Renal elimination of iron, occurring in the first 4 hafter injection, corresponds to less than 5% of the total body clearance. After 24 h the plasma levels of iron were reduced to the pre-dose iron level and about 75% of the dosage of sucrose was

Indicated in the treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy.

DOSAGE AND ADMINISTRATION:

DUSINE ARIU autiment in Adult and the Edward and a Adult and the Edward and the E according to the total iron deficit calculated with the following formula:

Total iron deficit [mg] = body weight [kg] x (target Hb - actual Hb) [g/]] x 0.24* +

Total iron detect (mg) = 000 y weight (spt) x (sept cur = www.mry (sp y n.v.c. = dept iron (mg) = dept iron (mg) = 130 g/L and depot iron = 15 mg/kg body weight = 35 kg body weight and above target Hb = 150 g/L and depot iron = 500 mg = 15 mg/L and depot iron = 500 mg = 15 mg/L and depot iron = 0.34%; Blood volume = 7% of body weight; Factor 0.24 = 0.0034 x 0.07 x 1000 (tron content of hemoglobin = 0.34%; Blood volume = 7% of body weight; Factor 1000 = conversion from g to mg)

The total amount of Iron sucrose Injection required is determined from above calculation Alternatively, the total amount of Iron Sucrose Injection required in mL is determined from the following formula or dosage

Total amount of Iron Sucrose Injection required ImL1 = Total iron deficit Imgl

To convert Hb(mM) to Hb(g/L), multiply the former by 16.1145.

Maximum recommended dose:

The total single dose must not exceed 200 mg of iron given not more than three times per week. If the total necessary dose exceeds the maximum allowed single dose, then the administration has to be solid

The use of Iron sucrose Injection has not been adequately studied in children and, therefore, Iron sucrose Injection is not recommended for use in children

METHOD OF ADMINISTRATION:

Administration:

Iron sucrose Injection must only be administered by the intravenous route. This may be by a slow intravenous injection or by an intravenous drip infusion. Before administering the first dose to a new patient, a test dose of Iron sucrose Injection should be given. Iron sucrose Injection must not be used for intramuscular injection.

INTRAVENDUS DRIP INFUSION-

Iron sucrose Injection must be diluted only in sterile 0.9% w/v sodium chloride solution:

- 5 mL Iron sucrose Injection (100 mg iron) In max. 100 mL sterile 0.9% w/v sodium chloride solution 10 mL Iron sucrose Injection (200 mg iron)
- In max, 200 ml. sterile 0.9% w/v sodium chloride solution

For stability reasons, dilutions to lower fron sucrose injection concentrations are not permissible.

Dilution must take place immediately prior to infusion and the solution should be administered as follows:

- 100 mg iron (5 mL iron sucrose Injection) in at least 15 minutes
 200 mg iron (10 mL iron sucrose Injection) in at least 30 minutes
 The first 25 mg of iron (i.e. 25 mL of solution) should be infused as a test dose over a period of 15 minutes. If no adverse

reactions occur during this time, then the remaining portion of the infusion should be given at an infusion rate of not more than 50 ml in 15 minutes

INTRAVENDUS IN JECTION

Iron sucrose Injection may be administered by slow intravenous injection at a rate of 1 mL undiluted solution per minute (i.e. 5 minutes per ampoule) and not exceeding 2 ampoules Iron sucrose Injection (200 mg iron) per injection. Before administering a slow intravenous injection, a test dose of 1 mL (20 mg of iron) should be injected slowly over a period of 1 to 2 minutes. If no adverse events occur within 15 minutes of completing the test dose, then the rema portion of the injection may be given.

Injection into Dialyser:

Iron sucrose Injection may be administered during a hemodialysis session directly into the venous limb of the dialyser under the same procedures as those outlined for intravenous injection.

CONTRAINDICATIONS:

he use of fron sucrose injection is contraindicated in cases of

 Known hypersensitivity to Iron sucrose Injection or any of its excipients. Anemias not attributable to iron deficiency.

Iron overload or disturbances in utilization of iron

Patients with a history of asthma, eczema or other atopic allergy, because they are more susceptible to experience allergic reactions

Pregnancy first trimester

WARNINGS

WARMINGS.

Parenterally administered fron preparations can cause allergic or anaphylactold reactions, loss of consciousness, collapse and hypotension, which may be potentially fatal. Therefore, treatment for serious allergic reactions and facilities

with the established cardiopulmonary resuscitation procedures should be available. In patients with liver dystunction, parenteral inan should only be administered after careful risk/benefit assessment. Parenteral from administration should be avoided in patients with hepatic dysfunction where iron overbood is a procipitating factor, in particular Porphyria Cutanea Tarda (PCT). Careful monitoring of iron status is recommended to avoid iron

GENERAL:

Because body iron excretion is limited and excess tissue iron can be hazardous, caution should be exercised to withhold secause oney rion excretion is immed and excess issue iron can be hazardous, caution should be exercised to withhold iron administration in the presence of edivence of lissue iron overlado. Patients require periodic monthing of hematologic and and anemia parameters (permoglobin, hematocit, serum ferrifin and transferrin saturation), from therapy should be withheld in patients with evidence of iron overladd. Transferrin saturation values increase rapidly after IV administration of iron sucrose; thus, serum iron values may be reliably obtained 48 hours after IV dosing.

Parenteral fron must be used with caution in case of acute or chronic infection. It is recommended that the administration of iron sucrose is stopped in patients with ongoing bactermia. In patients with chronic infection a risk/benefit evaluation has to be performed, taking into account the suppression of erythropolesis. Hypotensive episodes may occur if the injection is administered too rapidly. Allergic reactions, sometimes involving

arthraigia, have been more commonly observed when the recommended dose is exceeded.

Paravenous leakage must be avoided because leakage of Iron sucrose Injection at the injection site may lead to pain, inflammation, itsee necrosis and brown discoloration of the skin.

Caution required in pregnancy, safety has not been established to administer in nursing mother, children and geriatric.

INTERACTION WITH OTHER MEDICAMENTS:

As with all parenteral iron preparations, Iron sucrose Injection should not be administered concomitantly with oral iron preparations since the absorption of oral iron is reduced. Therefore, oral iron therapy should be started at least 5 days after the last injection of Iron sucrose Injection

PREGNANCY AND LACTATION:

Data on a limited number of exposed pregnancies indicated no adverse effects of fron sucrose hipection USP on pregnancy or on the health of the fetus/newborn child. No well-controlled studies in pregnant women are available to date. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development.

Nevertheless, risk/benefit evaluation is required.

Never unless, insofereint is valuation is required. from sucrose injection should only be used in pregnant women in whom oral iron is ineffective or cannot be tolerated and the level of anemia is judged sufficient to put the mother or letus at risk. Non-metabolized from sucrose injection is unlikely to pass into the mother's milk. No well-controlled clinical studies are

available to date. Animal studies do not indicate direct or indirect harmful effects to the nursing child.

ADVERSE DRUG REACTIONS:

AUVENSE UNIDH NEAL HUNS: The most frequently reported adverse drug reactions (ADRs) of iron sucrose injection in clinical trials were transient taste perversion, hypotension, fever and shivering, injection safe reactions and nausea, occurring in 0.5 to 1.5% of the patients. Non-serious anaphylactoid reactions courred rarely. In general anaphylactoid, reactions are potentially the most serious adverse reactions. In clinical trials, in Globwing adverse of require actions have been reported in temporal relationship with the administration of

Iron sucrose Injection, with at least a possible causal relationship: Nervous system disorders

Common (> 1/100, < 1/10): transient taste perversions (in particular metallic taste).

Uncommon (> 1/1000, < 1/100): headache; dizziness Rare (> 1/10000, < 1/1000): paraesthesia.

Cardiovascular disorders
Uncommon (> 1/1000, < 1/1000): hypotension and collapse; tachycardia and palpitations.

Respiratory, thoracic and mediastinal disorders Uncommon (> 1/1000, < 1/100): bronchospasm, dyspnea.

Gastrointestinal disorders

Uncommon (> 1/1000, < 1/100); nausea; vomiting; abdominal pain; diarrhea. Skin and subcutaneous tissue disorders
Uncommon (> 1/1000, < 1/100); pruritus; urticaria; rash, exanthema, erythema.

Musculoskeletal, connective tissue and bone disorders Uncommon (> 1/1000, < 1/100): muscle cramps, myalgia

General disorders and administration site disorders nmon (> 1/1000, < 1/100): fever, shivering, flushing; chest pain and tightness. Injection site disorders such as

superficial phlebitis, burning, swelling. Rare (> 1/10000, < 1/1000): anaphylactoid reactions (rarely involving arthralgia); peripheral edema; fatigue, asthenia;

Moreover, in spontaneous reports, the following adverse reactions have been reported: Isolated cases: reduced level of consciousness, light-headed feeling, confusion; angloedema; swelling of joints, hyperhidrosis, and back-pain.

OVERDOSE AND TREATMENT:

Overdosage can cause acute iron overloading which may manifest itself as hemosiderosis. Overdosage should be treated, if required, with an iron chelating agent.

CAUTION:

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

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph. Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION-

Store at temperatures not exceeding 30°C. Protect from light. Do not freeze.

KEEP OUT OF REACH OF CHILDREN.

FOR SINGLE USE ONLY.

AVAILABILITY:

USP Type I Amber Glass Ampoule x 5 mL (Box of 1 PVC Tray x 5's)

DRP-7844-05

Date of First Authorization: May 28, 2020 Date of Revision of Package Insert: Oct 05, 2020

> Manufactured by: BIORX PHARMA LABS LLP 809 Kerala GIDC Bavla, Ahmedabad 382220, India

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