Preparation and administration

1. Withdraw the required dose.
2. The solution should be brown and free of sediment. Inspect visually for particulate matter or discoloration prior to administration and discard if present.
3. Initial test dose (prior to first dose only): give 1mL of undiluted injection by IV injection over 1-2 minutes. Observe the patient carefully for signs of allergic reaction for at least 15 minutes; if no adverse effects are seen, give the remainder of the injection.
4. Give undiluted injection by IV injection at a maximum rate of 1mL/minute (i.e. 5 minutes per ampoule).

Common and serious undesirable effects

Other: Pruritus; urticaria; rash; exanthema; erythema; arthralgia (more common if recommended dose exceeded); headache; dizziness; confusion; metallic taste; pyrexia; shivering; GI disturbances (nausea, vomiting, abdominal pain, diarrhoea); ″pulse and palpitations; chest pain; peripheral oedema; hyperhidrosis.

Chronic repeated administration of iron at high doses can cause liver accumulation, leading to fibrosis as a result of inflammation.

Significant interactions

Iron sucrose may ″levels or effect of the following drugs (or ″side-effects):

dimercaprol (avoid combination -- may result in serious toxicity).

Iron sucrose may levels or effect of oral iron salts (absorption - do not start within 5 days of parenteral treatment).

ADVERSE REACTIONS

Nausea, vomiting, metallic taste; constipation, diarrhoea, dark stools, epigastric pain, gastrointestinal irritation; long-term or excessive administration may cause haemosiderosis; allergic reaction; back pain; staining of teeth.

Parenteral: Pain at injection site, sterile abscess.

PRECAUTIONS

Observe patien for at least 1 hour for signs of hypersensitivity, respiratory distress, tachycardia or back/chest pain; should not be administered for longer than 6 months; pregnancy, peptic ulcer; hypotension; regional enteritis, ulcerative colitis, intestinal strictures, diverticula; interactions.

PREGNANCY:-

Pregnancy Category B.

There are no adequate and well-controlled studies in pregnant women. In animal reproduction studies, iron sucrose was administered intravenously to rats and rabbits during the period of organogenesis at doses up to 13 mg/kg/day of elemental iron (half or equivalent to the maximum recommended human dose based on body surface area, respectively) and revealed no evidence of harm to the fetus due to iron sucrose. Because animal reproductive studies are not always predictive of human response, Iron Sucrose Injection USP should be used during pregnancy only if clearly needed

ADVERSE EFFECTS

For parenteral iron, see Iron Dextran, Iron sucrose injection is strongly alkaline and must not be given subcutaneously or intramuscularly. UK (but not US) licensed product information contra-indicates its use in patients with a history of asthma, eczema, anaphylaxis. Or other allergic disorders.

OVERDOSAGE

Symptoms to watch for: Acute iron overloads which may appear as haemosiderosis.

Antidote: Iron chelation therapy can be used.

Storage : Store in a cool, dry & dark place. Protected from light. Do not allow to freeze. Improper Storage may deteriorate the product

Keep the medicine out of reach of children.

Presentation : Each ml contains 20 mg of elemental Iron.

Manufactured by:

AMERICAN REMEDIES©
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
ICO: American Remedies LLC, DE, USA

Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A,
Harihar Complex, Bhiwandi, Mumbai - 421302
At: Vill. Surajpur Nahan Road Paonta Sahib,
Distt. Sirmour, Himachal Pradesh-173025
E-mail: info@americanremedies.in

WHO GMP

For the use only of a Registered Medical Practitioner or a hospital or a laboratory

℞ Iron Sucrose Injection USP

AMERICAN Sucrocan
Injection

FOR IV USE ONLY

Composition:-

Each ml Contains:-

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

Description:-

Iron sucrose injection, USP, an iron replacement product, is a brown, sterile, aqueous, complex of polynuclear iron (III)-hydroxide in sucrose for intravenous use. Iron sucrose injection has a molecular weight of approximately 34,000 to 60,000 daltons and a proposed structural formula:

$$[Na_2Fe_5O_8(OH)\cdot 3(H_2O)]_n\cdot m(C_{12}H_{22}O_{11})$$

Where: n is the degree of iron polymerization and m is the number of sucrose molecules associated with the iron (III)-hydroxide.

Each mL contains 20 mg elemental iron as iron sucrose in water for injection. Iron Sucrose Injection USP is available in 5 mL single-dose vials (100 mg elemental iron per 5 mL), The drug product contains approximately 30% sucrose w/v (300 mg/mL) The osmolarity of the injection is 1,250 mOsmol/L.

PHARMACOLOGY

Pharmacokinetics

Iron sucrose is rapidly cleared from the plasma after intravenous injection with a terminal half-life of about 6 hours. A competitive exchange of iron takes place from the iron sucrose complex to the iron -binding protein transferrin. About 5% of a dose is eliminated via the kidneys in the first 4 hours after a dose.

Direction for Administration

USES AND ADMINISTRATION

Iron sucrose is used as a source of iron for adults with iron-deficiency anaemia. Including those with chronic kidney disease. It is given when oral iron therapy is ineffective or impractical, by slow intravenous injection, or intravenous infusion; when used in haemodialysis patients, it may be given into the venous limb of the dialyser. The dose is calculated according to body-weight and iron deficit. In the UK, the maximum single dose mustnot exceed 200 mg of iron given not more than three times weekly. The dose is split if the total necessary dose exceeds the maximum single dose. The dose may be given undiluted at a rate of 20 mg/minute. Alternatively, it is diluted to a minimum concentration of 1 mg/mL in sodium chloride 0. 9 % and given at a rate not exceeding 50 mL per 15 minutes.

In the USA for patients with chronic kidney disease and on haemodialysis, a dose of 100 mg may be given per consecutive haemodialysis session, either undiluted as a slow intravenous injection over 2 to 5 minutes, or diluted in up to 100 mL sodium chloride 0. 9% and infused over at least 15 minutes. For peritoneal dialysis patients, two infusions of 300 mg over 1.5 hours are given 14 days apart, followed by an infusion of 400 mg over 2.5 hours 14 days later. The doses are diluted in a maximum of 250 mL of sodium chloride 0.9 %. For patients with chronic kidney disease but not on dialysis, a dose of 1g is given over a 14- day period, as a 200 mg slow undiluted intravenous injection over 2 to 5 minutes on 5 separate occasions within this time. Iron sucrose has also been given orally.