Bisleri®-S 100mg/5ml Injection

(Iron Sucrose Complex)

For IV use only

DESCRIPTION:

Bisleri®-S (Iron sucrose complex) injection is an aqueous complex of iron (III) hydroxide with sucrose. **Bisleri®-S** is a dark brown, non-transparent aqueous solution

CHEMICAL STRUCTURE:

Bisleri®-S structural formula is:

$[Na_2Fe_5O_8(OH).3(H_2O)]n).m(C_{12}H_{22}O_{11})$

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

COMPOSITION:

Each 5ml contains:

Iron sucrose complex MS

equivalent to Elemental Iron.....100mg i.e. each ml contains 20mg elemental iron as iron sucrose

CLINICAL PHARMACOLOGY:

In healthy adults treated with intravenous doses of **Bisleri®-S** Injection (iron sucrose complex), its iron component exhibited first-order kinetics:

- Elimination half life T1/2 — **6 hours**
- Total clearance — **1.2 liters per hour**
- Non-steady-state apparent volume of distribution — **10.0 liters**
- Steady-state apparent volume of distribution — **7.9 liters**

Since iron disappearance from the 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 **Bisleri®-S** Injection (iron sucrose complex) as compared with healthy individuals

Distribution:

In healthy adults, the iron component of iron sucrose complex appears to distribute mainly in the blood and to some extent in extravascular fluid

Metabolism:

Iron sucrose is dissociated into iron and sucrose by the reticuloendothelial system

Elimination:

The sucrose component is eliminated mainly by urinary excretion. Some iron is also eliminated in the urine (approximately 5%)

INDICATIONS:

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

CONTRA-INDICATIONS:

The use of **Bisleri®-S** is contra-indicated in cases of:

- Anemias not attributable to iron deficiency
- Iron overload or disturbances in utilization of iron
- A history of hypersensitivity to parenteral iron preparations
- Patients with a history of asthma, eczema or other atopic allergy, because they are moresusceptible to experience allergic reactions
- History of cirrhosis or hepatitis or the presence of serum transaminases greater than three times the upper limit of normal values
- First trimester of pregnancy

ADVERSE EVENTS:

Adverse reactions may include hypotension, muscle cramps, nausea, headache, graft complication, vomiting, dizziness, hypertension, chest pain and diarrhea

INTERACTION WITH OTHER MEDICATION:

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

PRECAUTIONS:

Pregnancy Category B:

Reproductive toxicity studies in animals have shown that iron sucrose is not teratogenic or embryocidal in non-anemic pregnant animals. However the use of parenteral iron preparations during the first three months has to be discouraged. During the second and third term the application has to be done with caution

Nursing Mothers:

Iron sucrose complex is excreted in milk of rats. 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 complex is administered to a nursing woman

Paediatric Use:

Safety and effectiveness of iron sucrose complex in paediatric patients have not been established

DOSAGE AND ADMINISTRATION

Normal dosage:

Adults and Elderly:

5 - 10ml (100 to 200mg iron) once to three times a week depending on the hemoglobin level

Children:

There is limited data on children under study conditions. If there is a clinical need, it is recommended not to exceed 0.15ml (3mg iron/kg body weight) once to three times a week

180 mm

150 mm

depending on the hemoglobin level

Maximum tolerated single dose:
Adults and Elderly:
As injection: 10ml (200mg iron) injection in at least 10 minutes
As infusion: When the clinical situation demanded, doses up to 500mg have been administered.
The maximum tolerated single dose is 7mg iron per kg body weight given once per week but not exceeding 500mg iron

ADMINISTRATION:
Bisleri-S is exclusively to be administered intravenously by drip infusion
Before administration a test dose should be administered. If any allergic reaction or intolerance occurs during administration, therapy must be stopped immediately
Bisleri-S may preferably be administered by drip infusion (in order to reduce the risk of hypotensive episodes). 1ml (20mg iron) has to be diluted exclusively in max. 20ml of 0.9% w/v NaCl solution, immediately prior to infusion (i.e. 5ml in max 100ml 0.9% w/v NaCl up to 25ml in max. 500ml 0.9% w/v NaCl). The solution should be infused at a rate of:

- 100ml in at least 15min
- 200ml in at least 30min
- 300ml in at least 1.5h
- 400ml in at least 2.5h
- 500ml in at least 3.5h

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE:
Iron sucrose should only be administered where the indication is confirmed by appropriate investigations (e.g serum ferritin, or hemoglobin (Hb), or hematocrit, or erythrocyte count, or red cell indices MCV, MCH, and MCHC)
Parenterally administered iron preparations can cause allergic or anaphylactoid reactions. In the case of a mild allergic reaction, antihistamines should be administered; in the case of a serious anaphylactoid reaction adrenaline should be administered immediately. Patients with bronchial asthma, with low iron binding capacity and / or folic acid deficiency are particularly at risk of an allergic or anaphylactoid reaction. Iron sucrose must be used with care in patients with serious hepatic dysfunction. Hypotensive episodes may occur if injection is administered too rapidly

OVERDOSAGE:
Bisleri-S should not be administered to patients with iron overload and should be discontinued when serum ferritin levels equal or exceed normal values otherwise can lead to hemosiderosis Symptoms like hypotension, dyspnea, headache, vomiting, nausea, dizziness, joint aches, paresthesia, abdominal and muscle pain, edema, and cardiovascular collapse may appear due to either overdosage or infusing Bisleri-S too rapidly
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

INCOMPATIBILITIES:
Bisleri-S must only be mixed with 0.9% w/v NaCl solution. No other intravenous dilution solutions and therapeutic agent should be used as there is a potential for precipitation and/or interaction. The compatibility with containers other than glass, polyethylene and PVC is not known

STABILITY:
See expiry on the pack

PRESENTATION:
Bisleri-S 100mg/5ml Injection in pack of 5's

INSTRUCTIONS:
Keep out of reach of children
Avoid exposure to heat, light and freezing
Store between 15 to 30°C
Improper storage may deteriorate the medicine

Caution: Injection should not be used if container is leaking, solution is cloudy or it contains un-dissolved particle(s)

بِسلری-ایس ۱۰۰ ملی گرام/۵ ملی لیٹر انجکشن

(آئرن سکروز کمپلیکس)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

ہدایات: بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی اور منجمد ہونے سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ

کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

تنبیہ: انجکشن کے لیک ہونے، دھندلا ہونے یا اس میں کوئی غیر حل پزیر

شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
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www.samipharmapk.com

P002067/S

R.N-04/HA/04/16/Inj.

180 mm

150mm