Feroneph™

Iron Sucrose Injection 100 mg/5ml Ampoule

For Rapid Iron Replenishment

Product Description:

Feroneph 5 ml Ampoule: Each ml contains Ferric hydroxide in complex with sucrose equivalent to elemental Iron 20 mg

General Information:

Feroneph (iron sucrose injection, USP) 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 – 60,000 daltons

Each mL contains 20 mg elemental iron as iron sucrose in water for injection. Feroneph 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) and has a pH of 10.5-11.1. The product contains no preservatives. The osmolarity of the injection is 1,250 mOsmol/L.

Iron Sucrose is used as a source of iron in patients with iron deficiency anemia with chronic kidney disease (CKD), including those who are undergoing dialysis (hemodialysis or peritoneal) and those who do not require dialysis. Due to less side effects than iron dextran, iron sucrose is more preferred in chronic kidney disease patients.

Indication & Usage:

Feroneph is indicated in the treatment of iron deficiency anemia in the following patients:

- Hemodialysis dependent-chronic kidney disease (HDD-CKD) patients receiving an erythropoietin
- Peritoneal dialysis dependent-chronic kidney disease (PDD-CKD) patients receiving an erythropoietin.
- Non-dialysis dependent-chronic kidney disease (NDD-CKD) patients receiving anerythropoietin

- Other conditions where oral iron therapy is considered inadequate and parenteral iron therapy is indicated

Dosage and Administration:

The dosage of Feroneph is expressed in terms of mg of elemental iron. Each mL contains 20 mg of elemental iron.

Feroneph must only be administered intravenously either by slow injection or by infusion

- **Haemodialysis Dependent-Chronic Kidney Disease Patients (HDD-CKD)**: The recommended dose of Feroneph is 100 mg(5ml) administered one to three times per week, most patients will require a minimum cumulative dose of 1000 mg over 10 sequential dialysis sessions. Patient may continue to require therapy with Feroneph at the lowest dose necessary to maintain target level of haemoglobin, haematocrit & laboratory parameters of iron storage within acceptable limits

- **Slow Intravenous Injection**: In CKD patients, Feroneph may be administered undiluted as a 100 mg slow intravenous injection over 2 to 5 minutes or as an infusion of 100 mg, diluted in a maximum of 100 mL of 0.9% NaCl over a period of at least 15 minutes per consecutive hemodialysis session for a total cumulative dose of 1,000 mg.

- **Non-Dialysis Dependent-Chronic Kidney Disease Patients (NDD-CKD)**Feroneph 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.

- **Peritoneal Dialysis Dependent-Chronic Kidney Disease Patients (PDD-CKD):** Feroneph is administered as a total cumulative dose of 1,000 mg in 3 divided doses, given by slow intravenous infusion, within a 28-day period: 2 infusions of 300 mg over 1.5 hours 14 days apart followed by one 400 mg infusion over 2.5 hours 14 days later. The Feroneph dose should be diluted in a maximum of 250 mL of 0.9% NaCl.

Mechanism of action:

Following intravenous administration, iron sucrose is dissociated into iron and sucrose and the iron is transported as a complex with transferrin to target cells including erythroid precursor cells. The iron is then incorporated into hemoglobin as the cells mature into red blood cells.

Pharmacokinetic:

Absorption: Following intravenous doses of Iron sucrose its iron component exhibits first order kinetics with an elimination half-life of 6 h, total clearance of 1.2 L/h, non-steadystate 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,Iron sucrose appears to distribute mainly in blood and to some extent in extravascular fluid. Significant amount of the administered iron distributes in the liver, spleen and bone marrow

Metabolism and Elimination:
Following intravenous administration, iron sucrose is dissociated into iron and sucrose by the reticuloendothelial system. The sucrose component is eliminated mainly by urinary excretion.

Use in Specific Population:

Pregnancy: There are no adequate and well controlled studies in pregnant women, this drug should be used during pregnancy only if clearly needed.

Nursing Mother: 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 sucroseisadministered to a nursing woman.
Pediatric Use: Safety and effectiveness of Iron Sucrosein pediatric patients has not been established

Geriatic Use: No overall differences in safety were observed between older and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Contraindication: The use of Feronephis contraindicated in patients with evidence of iron overload, in patients with known hypersensitivity to Feroneph or any of its inactive components, and in patients with anemia not caused by iron deficiency.

Warning & Precaution: Hypersensitivity reactions have been reported with injectable iron products

General: Patients receiving Feronephrequire periodic monitoring of hematologic and hematinic parameters (hemoglobin, hematocrit, serum ferritin and transferrin saturation). Iron therapy should be stopped in patients with evidence of iron overload.

Hypersensitivity Reactions: Several cases of mild or moderate hypersensitivity reactions were observed in clinical studies of iron sucrose

Hypotension: Hypotension has been reported frequently in hemodialysis dependent-chronic kidney disease patients receiving intravenous iron. Hypotension also has been reported in non-dialysis dependent and peritoneal dialysis dependent-chronic kidney disease patients receiving intravenous iron.

Drug Interaction:

Like other parenteral iron preparations, Feronephmay be expected to reduce the absorption of concomitantly administered oral iron preparations.

Adverse Reactions:

Most common Iron sucrose adverse drug reaction

Area of Affect	Adverse Effect
Gastrointestinal	Nausea Vomiting Diarrhoea Abdominal Pain Constipation

General	Chest Pain Peripheral Edema Feeling Abnormal Infusion site burning Pyrexia
Vascular Disorders	Hypotension Hypertension
Infectious	Nasopharyngitis Upper respiratory tract infection
Nervous System Disorder	Headache Dizziness