Kidifer

Iron Sucrose Injection USP

Presentation
Kidifer IV Injection: Each ampoule contains 5 ml sterile solution of Iron Sucrose Injection USP equivalent to 100 mg elemental Iron (20 mg/ml).

Pharmacology
The therapeutic class of Iron Sucrose is haematinic. Iron Sucrose Injection USP is a brown, sterile, aqueous, complex of Polynuclear Iron (III) Hydroxide in Sucrose for Intravenous use.The drug product contains approximately 30% Sucrose w/v (300 mg/ml) and has a p^H of 10.5-11.1. Following intravenous administration of **Kidifer** (Iron Sucrose), Iron Sucrose is dissociated by the reticuloendothelial system into iron and sucrose. In 22 hemodialysis patients on erythropoietin (recombinant human erythropoietin) therapy treated with **Kidifer** (Iron Sucrose) containing 100 mg of iron, three times weekly for three weeks, significant increases in serum iron and serum ferritin and significant decreases in total iron binding capacity occurred four weeks from the initiation of **Kidifer** (Iron Sucrose) treatment. In healthy adults treated with intravenous doses of **Kidifer** (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-steady state apparent volume of distribution of 10.0 L and steady state apparent volume of distribution of 7.9 L. In healthy adults receiving intravenous doses of **Kidifer** (Iron Sucrose), its iron component appears to distribute mainly in blood and to some extent in extravascular fluid. Following intravenous administration of **Kidifer** (Iron Sucrose), Iron Sucrose is dissociated into iron and sucrose by the reticuloendothelial system. The sucrose component is eliminated mainly by urinary excretion.

Indications
Kidifer (Iron Sucrose) is indicated in the treatment of iron deficiency anemia in the following patients:
- Where there is a clinical need for a rapid Iron supply.
- In patients who can not tolerate oral Iron therapy or who are non-compliant.
- Non-dialysis dependent-chronic kidney disease (NDD-CKD) patients receiving an erythropoietin.
- Non-dialysis dependent-chronic kidney disease (NDD-CKD) patients not receiving an erythropoietin.
- Hemodialysis dependent-chronic kidney disease (HDD-CKD) patients receiving an erythropoietin.
- Peritoneal dialysis dependent-chronic kidney disease (PDD-CKD) patients receiving an erythropoietin.

It is also indicated in the treatment of Iron deficiency anaemia in patients undergoing surgical procedures, patients donating blood, postpartum patients.

Dosage & Administration
The dosage of **Kidifer** (Iron Sucrose) is expressed in terms of mg of elemental iron. Each ml contains 20 mg of elemental iron. Most CKD patients will require a minimum cumulative repletion dose of 1,000 mg of elemental iron, administered over sequential sessions, to achieve a favorable hemoglobin response and to replenish iron stores (ferritin, TSAT). Hemodialysis patients may continue to require therapy with **Kidifer** (Iron Sucrose) or other intravenous iron preparations at the lowest dose necessary to maintain target levels of hemoglobin, and laboratory parameters of iron storage within acceptable limits. **Kidifer** (Iron Sucrose) must only be administered intravenously either by slow injection or by infusion.

Recommended Adult Dosage:
Hemodialysis Dependent-Chronic Kidney Disease Patients (HDD-CKD)
Kidifer (Iron Sucrose) 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% Sodium Chloride 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)
Kidifer (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 **Kidifer** (Iron Sucrose), diluted in a maximum of 250 ml of 0.9% Sodium Chloride, over a period of 3.5-4 hours on day 1 and day 14; hypotension occurred in 2 of 30 patients treated.

Peritoneal Dialysis Dependent-Chronic Kidney Disease Patients (PDD-CKD)
Kidifer (Iron Sucrose) 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 **Kidifer** (Iron Sucrose) dose should be diluted in a maximum of 250 ml of 0.9% Sodium Chloride.
Calculation of Dosage:
The dosage has to be in individually adapted according top the total Iron deficit calculated with the following formula:
Total Iron deficit [mg]= body weight [kg] x (target Hb-actual Hb)[g/l]x 0.24*+depot Iron[mg]
Up to 35 kg body weight: target Hb = 130g/l resp. depot Iron = 15 mg/kg body weight
Above 35 kg body weight: target Hb = 150g /l resp. depot Iron =500 mg
*Factor 0.24= 0.0034x 0.07x1000(Iron content of hemoglobin ≅ 0.34% blood volume ≅ 7% of body weight/Factor 1000= conversion from g to mg)
The total amount of Kidifer to be administratered(in ml)= Total Iron deficit [mg]/20 mg/ml
(1 ampoule of Kidifer corresponds to 5 ml)

Calculation of No. of ampoules required for different body weight and different hemoglobin level

Hb Level	5 kg	10 kg	15 kg	20 kg	25 kg	30 kg	35 kg	40 kg	45 kg	50 kg	55 kg	60 kg	65 kg	70 kg	75 kg	80 kg	85 kg	90 kg
Hb 60 g/l	1.5	3	5	6.5	8	9.5	12.5	13.5	15	16	17	18	19	20	21	22.5	23.5	24.5
Hb 75 g/l	1.5	3	4.5	5.5	7	8.5	11.5	12	13	14	15	16	16.5	17.5	18.5	19.5	20.5	21.5
Hb 90 g/l	1.5	2.5	3.5	5	6	7.5	10	11	11.5	12	13	13.5	14.5	15	16	16.5	17	18
Hb 105 g/l	1	2	3	4	5.5	6.5	9	9.5	10	10.5	11	11.5	12	12.5	13	13.5	14	14.5

If the total necessary dose exceeds the maximum allowed single dose, then the administration has to be spilt. If no response of the hematological parameters is observed after 10 to 2 weeks the original diagnosis should be reconsidered.

Calculation of dosage for Iron replacement secondary to blood loss and to support autologous blood donation:The required **Kidifer** dose to compensate the Iron deficit is calculated according to the following formula: if the quantity of blood is known: The administration of 200 mg IV Iron (=10 ml **Kidifer**) results in an increase in hemoglobin which is equivalent to 1 unit blood (=400 ml with 150 g/l Hb content). Iron to be replaced [mg] = number of blood lost x 200 or Amount of **Kidifer** needed(ml) = number of blood units lost x 10. If the HBb level is reduced: Use the previous formula considering that the depot Iron does not need to be restored. Iron to be replaced [mg] = body weight [kg] x 0.24 x (target Hb-actual Hb) [g/l] e.g body weight 60kg, Hb deficit = 10 g be replaced ≅ 150 mg ⇒ 7.5 ml **Kidifer** needed.

Normal Dosage:

Adults and Elderly: 5-10 ml **Kidifer** (100-200 mg 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 0.15 ml Kidifer(3 mg Iron) **Kidifer** (3mg Iron) per kg body weight once to three times per week depending on the hemoglobin level.

Contraindications
The use of **Kidifer** (Iron Sucrose) is contraindicated in patients with evidence of iron overload, in patients with known hypersensitivity to **Kidifer** (Iron Sucrose) or any of its inactive components, and in patients with anemia not caused by iron deficiency.
Side Effects
The following possible side effects have been reported following the administration of **Kidifer** (Iron Sucrose):
Temporary changes in taste (eg metallic taste), Nausea, stomach pain, diarrhea, vomiting, Muscle pain, cramps, Irregular heart beat, Burning and swelling at injection site, Shivering, Fever, Tiredness, Itchy skin and rash.

Precautions
Iron Sucrose should be administered with caution in patients with asthma, eczema, other atopic allergies or allergic reaction to other parenteral Iron preparations, low binding capacity and/or folic acid deficiency, liver dysfunction, acute or chronic infection.
Baseline tests: Ensure Hgb, Hct, serum ferritin and transferrin saturation is determined before starting therapy and periodically during treatment. Note that serum Iron levels may be reliably obtained 48 hours after IV dosing.
Blood Pressure: Monitor Blood Pressure during infusion. If hypotension occurs, slow the rate of infusion. If hypotension continues, discontinue infusion and be prepared to treat appropriately.
Discontinue oral Iron preparations before administering parenteral Iron products. Co-administration of parenteral Iron preparations may reduce absorption of oral Iron.The dose will be in terms of elemental Iron. For IV administration only. Not for intradermal, subcutaneous, IM, or intra-arterial administration. Do not administer more than 3 times/week. IV infusion for elderly should be diluted in 100 ml of 1 vial of 0.9% Sodium Chloride and should be infused over 15 minutes. Discard any unused diluted solution. Do not save unused solution for future use. Do not administer if particulate matter or discoloration noted.

Drug Interactions
Drug-drug interactions involving **Kidifer** (Iron Sucrose) have not been studied. However, like other parenteral iron preparations, **Kidifer** (Iron Sucrose) may be expected to reduce the absorption of concomitantly administered oral iron preparations.

Use in Pregnancy and Lactation
Pregnancy Category B. Nursing Mothers: **Kidifer** (Iron Sucrose) 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 **Kidifer** (Iron Sucrose) is administered to a nursing woman.

Over Dose
Kidifer (Iron Sucrose) should not be given to people with iron overload and should be stopped when serum ferritin levels equal or exceed established guidelines.

Storage Conditions
Store in original carton and below 25° C. Do not freeze. Keep out of the reach of children.

Commercial Pack
Kidifer IV Injection: Each box contains 1 blister pack of an ampoule of 5 ml sterile solution of Iron Sucrose Injection with Sterile Solution of 100 ml 0.9% Sodium Chloride (Normal Saline), a sterile disposable syringe, One infusion set, an alcohol pad and a first aid band.

Manufactured by :
GENERAL Pharmaceuticals Ltd.
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