Only for the use of Medical Professionals

Irosuc®

Iron Sucrose injection

Description

Irosuc® is a preparation of Iron Sucrose which is an aqueous complex of polynuclear iron (III) hydroxide in sucrose. 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. Iron in the precursor cells is incorporated into hemoglobin as the cells mature into red blood cells.

Indications

Irosuc® is indicated for the treatment of iron deficiency in the following indications:

- Where there is a clinical need for a rapid iron supply.
- In patients who cannot tolerate oral iron therapy or who are non-compliant.
- In active inflammatory bowel disease where oral iron preparations are ineffective.
- 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.
- In the treatment of iron deficiency anemia in patients undergoing surgical procedures, patients donating blood, postpartum patients.

Dosage and administration

***Administration*: Irosuc®** has exclusively to be administered intravenously by drip infusion, by slow injection or directly into the venous limb of the dialyser and is not suitable for intramuscular use and for total dose infusion (TDI), where the full dose of iron required, representing the patient's total iron deficit is administered in one complete infusion. Before administration of the first therapeutic dose, a test dose should be given. If any allergic reactions or intolerance occurs during administration, the therapy must be stopped immediately.

***Intravenous injection:* Irosuc®** can be administered undiluted by slow intravenous injection at the recommended rate of 1 ml **Irosuc®** (20 mg iron) per minute [5 ml **Irosuc®** (100 mg iron) in 2 to 5 minutes]. A maximum of 10 ml **Irosuc®** (200 mg iron) can be injected per injection. Before administration of the therapeutic dose in a new patient a test dose of 1 ml **Irosuc®** (20 mg iron) in adults and in children with a body weight greater than 14 kg and half the daily dose (1.5 mg iron/kg) in children with a body weight less than 14 kg should be injected over 1 to 2 minutes. If no adverse reactions occur within a waiting period of 15 minutes, the remaining portion of the injection can be administered at recommended speed. After an injection, the arm of the patients should be extended.

***Infusion*: Irosuc®** should preferably be administered by drip infusion (in order to reduce the risk of hypotensive episodes and paravenous injection) in a dilution of 1 ml **Irosuc®** (20 mg iron) in maximum 20 ml 0.9% w/v sodium chloride [5 ml (100 mg iron) in maximum 100 ml 0.9% w/v NaCl etc. up to 25 ml (500 mg iron) in maximum 500 ml 0.9% w/v NaCl]. Dilution must take place immediately prior to infusion and the solution should be administered as follows: 100 mg iron in at least 15 minutes; 200 mg iron in at least 30 minutes; 300 mg iron in at least 1.5 hours;
400 mg iron in at least 2.5 hours and 500 mg iron in at least 3.5 hours. For the administration of the maximum tolerated single dose of 7 mg iron/kg body weight, and infusion time of at least 3.5 hours has to be respected, independently of the total dose.

Before administration of the therapeutic dose in a new patient the first 20 mg iron in adults and in children with a body weight greater than 14 kg and half the daily dose (1.5 mg iron/kg) in children with a body weight less than 14 kg should be infused over 15 minutes as a test dose. If no adverse reactions occur, the remaining portion of the infusion can be administered at recommended speed.

Injection into dialyser: **Irosuc®** may be administered directly into the venous limb of the dialyser under the same conditions as for intravenous injection.

Non-dialysis dependent-chronic kidney disease patients (NDD-CKD): **Irosuc®** is administered as a total cumulative dose of 1000 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.

Hemodialysis dependent-chronic kidney disease patients (HDD-CKD): **Irosuc®** 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 % w/v NaCl over a period of at least 15 minutes per consecutive hemodialysis session for a total cumulative dose of 1000 mg.

Peritoneal dialysis dependent-chronic kidney disease patients (PDD-CKD): **Irosuc®** is administered as a total cumulative dose of 1000 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 **Irosuc®** dose should be diluted in a maximum of 250 ml of 0.9 % w/v NaCl.

Note: Do not mix iron sucrose with other medications or add to parenteral nutrition solutions for intravenous infusion. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit.

Calculation of dosage: The dosage has to be individually adapted according to 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 = 130 g/L resp. depot iron = 15 mg/kg body weight. Above 35 kg body weight: target Hb = 150 g/L resp. depot iron = 500 mg.
*Factor 0.24 = 0.0034 x 0.07 x 1000 (iron content of hemoglobin ≅ 0.34%/blood volume ≅ 7% of body weight/factor 1000 = conversion from gm to mg)

$$\text{Total amount of } \textbf{Irosuc®} \text{ to be administered (in ml)} = \frac{\text{Total iron deficit [mg]}}{\text{20 mg/ml}}$$

Calculation of no. of ampoules (5 ml) 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 splitted. If no response of the hematological parameters is observed after 1 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 **Irosuc®** dose to compensate the iron deficit is calculated according to the following formulas: **If the quantity of blood lost is known:** The administration of 200 mg IV iron (= 10 ml **Irosuc®**) 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 units lost x 200 or amount of **Irosuc®** needed (ml) = number of blood units lost x 10. **If the Hb 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 60 kg, Hb deficit = 10 g/L = > iron to be replaced ≅ 150 mg = > 7.5 ml **Irosuc®** needed.

Normal dosage
Adults and elderly: 5 - 10 ml **Irosuc®** (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 exceed 0.15 ml **Irosuc®** (3 mg iron) per kg body weight once to three times per week depending on the hemoglobin level.

Pregnancy and lactation

Pregnancy
Iron sucrose is pregnancy category B. There are no adequate and well controlled studies in pregnant women. However, it should be used during pregnancy only if clearly needed.

Lactation
It is not known whether iron sucrose is excreted in human milk. Iron sucrose is secreted into the milk of lactating rats. Because many drugs are excreted in human milk, caution should be exercised when iron sucrose is administered to a nursing woman.

Side effects
The most common side effects of iron sucrose are diarrhea, nausea, vomiting, headache, dizziness, hypotension, pruritus, pain in extremity, arthralgia, back pain, muscle cramp, injection site reactions, chest pain and peripheral edema.

Contraindications
Iron sucrose is contraindicated in patients with known hypersensitivity to iron sucrose or any of the components of this preparation.

Warnings and 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 or folic acid deficiency, liver dysfunction, acute or chronic infection. 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. 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. Medication is administered 1 to 3 times per week. Do not administer more than 3 times per week. 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 interactions involving iron sucrose have not been studied. Iron sucrose injection should not be administered concomitantly with oral iron preparations since the absorption of oral iron is reduced. Even oral iron therapy should not be given until 5 days after last injection.

Overdose
No data are available regarding overdose of iron sucrose in humans. Excessive dosages of iron sucrose may lead to accumulation of iron in storage sites potentially leading to hemosiderosis. Do not administer iron sucrose to patients with iron overload.

Pharmaceutical precautions

- Store below 25^{O}C protected from light & moisture.
- Keep away from the reach of children.
- To be applied only on the prescription of a registered physician.

Presentation

Irosuc® injection for IV infusion: Each 5 ml ampoule contains Iron Sucrose USP equivalent to 100 mg elemental Iron (20 mg/ml)

Package quantities

Irosuc® injection for IV infusion: Each pack contains 1 ampoule of 5 ml Iron Sucrose injection USP, 1 bag of 100 ml Sodium Chloride BP 0.9% w/v (Normal saline as diluent), 1 infusion set, 1 disposable syringe (10 ml), 1 alcohol pad, 1 first aid bandage.

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