



For Swift Action

Qron

Iron Sucrose Injection USP 20 mg/ml

La Renon

► Background

- ◆ Patients with chronic kidney disease (CKD) are commonly iron deficient. Adequate iron stores are essential for achieving maximum benefit from erythropoietin-stimulating agents (ESAs).
- ◆ Decreased iron stores or decreased availability of iron are the most common reasons for resistance to the effect of these agents.
- ◆ Dialysis patients commonly suffer iron loss from gastrointestinal bleeding, blood drawing, and/or, most important with hemodialysis, the dialysis treatment itself. Hemodialysis patients lose an average of 1 to 2 g of iron per year.
- ◆ Thus, iron deficiency will tend to develop in virtually all dialysis patients unless supplemental iron therapy is given.
- ◆ Hemodialysis patients require both iron replacement and iron maintenance therapy to optimize management of anemia.
- ◆ Because oral iron supplements are relatively ineffective in correcting iron deficiency and maintaining iron balance, clinical practice guidelines recommend administration of intravenous iron.

► Why Qron ?



- ◆ Iron and EPO together make healthy red blood cells (RBC). An IV iron like Qron may help rise the amount of hemoglobin in RBCs.
- ◆ Hemoglobin is the substance in RBCs that helps carry oxygen throughout the body. Our cells need oxygen for Survival.
- ◆ When the kidneys fail, your body can no longer produce enough EPO on its own to create those RBCs, which is why dialysis patients are given extra EPO added to their own.
- ◆ Without enough iron you may suffer from iron deficiency anemia, a low amount of healthy RBCs commonly found in CKD. That's why an intravenous iron like Qron (Iron sucrose injection, USP) can be so important.

Iron sucrose in hemodialysis patients: Safety of replacement and maintenance regimens.

Background:

- ◆ Parenteral iron replacement and maintenance are frequently required in hemodialysis patients.
- ◆ However, serious adverse events have been reported after single doses of some intravenous iron products.
- ◆ This multicenter phase IV clinical trial examined the safety of iron sucrose for the treatment of iron deficiency and for the maintenance of iron sufficiency in hemodialysis patients.

Methods:

- ◆ This was a multicenter, open label, phase IV clinical trial in hemodialysis patients who required both erythropoietin (EPO) and iron supplementation in accordance with the National Kidney Foundation K/DOQI Clinical Practice Guidelines.
- ◆ In this safety study, iron sucrose was given in two dosing regimens. Iron deficient patients were treated with intravenous iron sucrose, 100 mg, during 10 consecutive hemodialysis sessions (replacement regimen).
- ◆ Iron replete patients were given iron sucrose, 100 mg intravenous (IV) over 5 minutes, weekly for 10 weeks (maintenance regimen).
- ◆ At the end of each 10-dose cycle, iron status was reassessed, and dosing during the subsequent cycle was based on the adequacy of iron stores as per Dialysis Outcome Quality Initiative (K/DOQI) Guidelines. With each dosing regimen, adverse events, if any, were recorded and described.

Results:

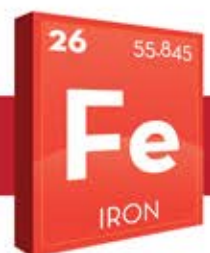
- ◆ Six hundred and sixty-five hemodialysis patients, including 80 who had experienced previous intolerance to other parenteral iron preparations, received a total of 8583 doses of iron sucrose.
- ◆ One hundred eighty-eight patients received more than one IV iron cycle (replacement, maintenance, or both). There were no serious or life-threatening drug-related adverse events.

Conclusion:

- ◆ This study demonstrates that iron sucrose is safe in the treatment of iron deficiency and the maintenance of adequate iron stores in EPO-treated dialysis patients, including those sensitive to iron dextran, ferric gluconate, or both.

Reference:

Kidney International, Vol. 66 (2004), pp. 1193–1198



Qron™

Iron Sucrose Injection USP 20 mg/ml

Description:

Qron (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.

Indication:

It is indicated for the treatment of iron deficiency anemia in patients with Chronic Kidney Disease (CKD).

Mechanism of Action:

Qron is an aqueous complex of poly-nuclear iron (III)-hydroxide in sucrose. Following intravenous administration, Qron 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 in the precursor cells is incorporated into hemoglobin as the cells mature into red blood cells.

Dosage:

Adult Patients with Hemodialysis Dependent -Chronic Kidney Disease (HDD-CKD):

Administer Qron 100 mg undiluted as a slow intravenous injection over 2-5 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. The usual total treatment course of Qron is 1000 mg.

Adult Patients with Non-Dialysis Dependent -Chronic Kidney Disease (NDD-CKD):

Administer Qron 200 mg undiluted as a slow intravenous injection over 2-5 minutes or as an infusion of 200 mg in a maximum of 100 mL of 0.9% NaCl over a period of 15 minutes.

Pediatric Patients (2 years of age and older) with HDD-CKD or with NDD-CKD:

For iron maintenance treatment: Administer Qron at a dose of 0.5 mg/kg, not to exceed 100 mg per dose, every two weeks for 12 weeks given undiluted by slow intravenous injection over 5 or diluted in 25 mL of 0.9% NaCl and administered over 5-60 minutes. Qron treatment may be repeated if necessary.

Administration:

Qron must be administered intravenously either by slow injection or by infusion.

Presentation:

Qron is available as a single dose of 5 ml ampoule.

La Renon Healthcare Pvt. Ltd.

207-208 ISCON Elegance | Circle P | Prahlad Nagar Cross Roads
S.G.Highway | Ahmedabad - 380015 | Gujarat | India.
Phone: +91-79-3046-1000 (30 Lines) | Fax: +91-79-3046-1001
E-Mail: info@larenon.com | www.larenon.com

