

Composition:

Revocit[™] Tablet: Each film coated tablet contains Ferric Citrate INN equivalent to Ferric Iron 210 mg.

Pharmacology:

Hyperphosphatemia in Chronic Kidney Disease (CKD) on Dialysis-

Ferric iron binds dietary phosphate in the GI tract and precipitates as ferric phosphate. This compound is insoluble and is excreted in the stool. By binding phosphate in the GI tract and decreasing absorption, ferric iron lowers the phosphate concentration in the serum.

Iron Deficiency Anemia in Chronic Kidney Disease (CKD) not On Dialysis-

Ferric Iron is reduced to the Ferrous form by Ferric reductase in the GI tract. After transport through the enterocytes into the blood, Ferrous Iron is oxidized to Ferric Iron. After that, Ferric Iron bounds to the plasma protein transferrin and can be incorporated into hemoglobin.

Indication:

- The control of serum phosphorus level in adult patients with chronic kidney disease on dialysis.
- The treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis.

Dosage & Administration:

Hyperphosphatemia in Chronic Kidney Disease on Dialysis:

- Starting dose is 2 tablets orally 3 times per day with meals.
- Adjust dose by 1 to 2 tablets as needed to maintain serum phosphorus at target levels, up to a maximum of 12 tablets daily. Dose can be titrated at 1 week or longer intervals.

Iron Deficiency Anemia in Chronic Kidney Disease not on Dialysis:

- Starting dose is 1 tablet orally 3 times per day with meals
- Adjust dose as needed to achieve and maintain hemoglobin goal, up to a maximum of 12 tablets daily or as directed by the physician.

Contraindication:

Iron overload syndromes (e.g. Hemochromatosis)

Warning & Precaution:

Iron absorption from this preparation may lead to excessive elevations in iron stores. May increase in serum ferritin and transferrin saturation (TSAT) levels.

Patients may require a reduction in dose or discontinuation of intravenous iron. Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. **Keep this product out of reach of children**. In case of accidental overdose, call a doctor or poison control center in hospital immediately.

Side Effect:

Most common adverse reactions are discolored feces, diarrhea, constipation, nausea, vomiting, cough, abdominal pain and hyperkalemia.

Use in Pregnancy & Lactation:

There is no available data on the use of Ferric Citrate in pregnant women & lactating mothers.

Use in Children & Adolescent:

The safety and efficacy of Ferric Citrate have not been established in Children & Adolescents.

Drug Interaction:

Doxycycline and Ciprofloxacin cannot be concomitantly used with Ferric Citrate. Doxycycline should be administered 1 hour prior to Ferric Citrate administration and Ciprofloxacin should be administered 2 hour prior to Ferric Citrate administration.

Overdose:

No data is available regarding overdose of Ferric Citrate. In patients with Chronic Kidney Disease, the maximum dose studied was 2,520 mg ferric iron per day (12 tablets of Ferric Citrate).

Storage Condition:

Store below 30°C. Keep all medicines out of reach of children.

How Supplied:

Revocit[™] **Tablet:** Each box contains 5 X 6 tablets in blister pack.

Manufactured by-



TM - Trade Mark