

Nepofer

Ferric Pyrophosphate Citrate

Only for use in dialysate

Presentation

Nepofer: Each 5 ml solution contains Ferric Pyrophosphate Citrate INN equivalent to 27.2 mg elemental Iron.

Description

Ferric Pyrophosphate Citrate solution is a mixed-ligand iron complex in which iron (III) is bound to pyrophosphate and citrate. Ferric Pyrophosphate Citrate solution is a clear, slightly yellow-green color sterile solution containing 27.2 mg iron (III) per 5 mL. Each Nepofer ampoule contains iron (7.5-9.0% w/w), citrate (15-22% w/w), pyrophosphate (15-22% w/w), phosphate (< 2% w/w), sodium (18-25% w/w) and sulfate (20-35%). One ampoule is added to 2.5 gallons (9.46 L) of bicarbonate concentrate.

Indications and Usages

Ferric Pyrophosphate Citrate is indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).

Dosage and Administration

Inspect Nepofer ampoule for signs of precipitation prior to mixing with the bicarbonate concentrate. Ferric Pyrophosphate Citrate should only be added to the bicarbonate concentrate and should not be added to acid concentrate mixtures. Add Ferric Pyrophosphate Citrate to bicarbonate concentrate used for generation of hemodialysate. The final concentration of Nepofer iron (III) in the final hemodialysate is 2 micromolar (110 mcg/L). Multiple ampoules can be added to the master bicarbonate mix at each center at a ratio of one (1) ampoule to each 2.5 gallons of bicarbonate concentrate.

Administer Ferric Pyrophosphate Citrate to patients at each dialysis procedure for as long as patients are receiving maintenance hemodialysis therapy for CKD.

Hemodialysis solutions should be used within 24 hours of the preparation of the Ferric Pyrophosphate Citrate /bicarbonate concentrate mixture.

Use in Pregnancy and Lactation

Pregnant women

Category C

Lactating mothers

It is not known whether Ferric Pyrophosphate Citrate is present in human milk or not.

Precautions

Hypersensitivity Reactions

Anaphylactic-type reactions, shock, hypotension, loss of consciousness and collapse can occur. Monitor patients for signs and symptoms of hypersensitivity during and after hemodialysis until he/she is clinically stable. Personnel and therapies should be immediately available for the treatment of serious hypersensitivity reactions.

Iron laboratory testing

Iron status should be determined on pre-dialysis blood samples. Post dialysis serum iron parameters may overestimate serum iron and transferrin saturation.

Drug Interactions

Formal drug interaction studies have not been performed for Ferric Pyrophosphate Citrate.

Contraindications

None

Overdose

No data are available regarding overdose of Ferric Pyrophosphate Citrate.

Side Effects

The most common side effects are headache, peripheral edema, asthenia, AV fistula thrombosis, urinary tract infection, AV fistula site hemorrhage, pyrexia, fatigue, hypotension, muscle spasms, pain in extremity, back pain, and dyspnea.

Storage

Keep in a cool and dry place, away from light. Keep out of reach of children.

Commercial Pack

Nepofer: Each box contains 1 amber ampoule of 5 ml solution of Ferric Pyrophosphate Citrate and one 5 ml disposable syringe.

Manufactured by

 **Incepta Pharmaceuticals Ltd**
Savar, Dhaka, Bangladesh

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