FIRST TIME GENERIC APPROVAL

Brand Name	Feraheme®
Generic Name	ferumoxytol
Drug Manufacturer	Sandoz Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

Jan 15,2021

LAUNCH DATE

July 16,2021

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 206604

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Ferumoxytol is an iron replacement product indicated for the treatment of iron deficiency anemia (IDA) in adult patients:

- who have intolerance to oral iron or have had unsatisfactory response to oral iron or,
- who have chronic kidney disease (CKD).

MECHANISMS OF ACTION

Ferumoxytol consists of a superparamagnetic iron oxide that is coated with a carbohydrate shell, which helps to isolate the bioactive iron from plasma components until the iron-carbohydrate complex enters the reticuloendothelial system macrophages of the liver, spleen and bone marrow. The iron is released from the iron-carbohydrate complex within vesicles in the macrophages. Iron then either enters the intracellular storage iron pool (e.g., ferritin) or is transferred to plasma transferrin for transport to erythroid precursor cells for incorporation into hemoglobin.

DOSE FORM AND STRENGTH

Injection: 510 mg iron per 17 mL (30 mg per mL) in single-dose vials

DOSE & ADMINISTRATION

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- The recommended dose of ferumoxytol is an initial 510 mg dose followed by a second 510 mg dose 3 to 8 days later.
- Administer ferumoxytol as an intravenous infusion in 50 to 200 mL 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP over at least 15 minutes.