RXADVANCE
2 Park Central Drive
Southborough, MA 01772

FIRST TIME GENERIC APPROVAL

Brand Name	Ferriprox®
Generic Name	deferiprone
Drug Manufacturer	Taro Pharmaceuticals Industries Limited

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

February 8, 2019

LAUNCH DATE

September 28, 2020

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA) 208800

DISPENSING RESTRICTIONS

Specialty Only

Overview

INDICATION FOR USE

Treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate

Approval is based on a reduction in serum ferritin levels. There are no controlled trials demonstrating a direct treatment benefit, such as improvement in disease-related symptoms, functioning, or increased survival.

Limitations of Use

- Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with other chronic anemias.

MECHANISMS OF ACTION

Deferiprone is a chelating agent with an affinity for ferric ion (iron III). Deferiprone binds with ferric ions to form neutral 3:1 (deferiprone:iron) complexes that are stable over a wide range of pH values. Deferiprone has a lower binding affinity for other metals such as copper, aluminum, and zinc than for iron.

DOSE FORM AND STRENGTH

500 mg film-coated tablets with a functional score

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DOSE & ADMINISTRATION

Initial: 25 mg/kg ABW PO three times daily, for a total daily dose of 75 mg/kg. Round dose to nearest 250mg.

Maximum: 33 mg/kg ABW PO three times daily, for a total daily dose of 99 mg/kg.