

## FIRST TIME GENERIC APPROVAL

<b>Brand Name</b>	Ferriprox®
<b>Generic Name</b>	deferiprone
<b>Drug Manufacturer</b>	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.

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