Prescriber Enrollment Form

Print Form

This Prescriber Enrollment Form must be completed before you can prescribe Ferriprox® (deferiprone). Ferriprox is available only through an exclusive distribution program called the Chiesi Total Care℠ Program.

Treating Physician Information

Full Name: _____

Practice Name: _____

Practice Address: _____

City: _____ State: _____ Zip: _____

Email: _____ Phone: _____ Fax: _____

Specialty: _____ ☐ ☐ ☐

Degree: MD DO NP with prescribing authority

State License #: _____ State of Issue: _____

DEA #: _____ NPI #: _____

Prescriber Acknowledgement

I understand:

- Ferriprox (deferiprone) is an iron chelator indicated for the treatment of transfusional iron overload due to:
  - thalassemia syndromes
  - sickle cell disease or other anemias
- Ferriprox Tablets are indicated in adult and pediatric patients ≥8 years of age; Ferriprox Oral Solution is indicated in patients ≥3 years of age.

Limitations of Use - Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.

- Fatal agranulocytosis can occur with Ferriprox use. Ferriprox can also cause neutropenia, which may foreshadow agranulocytosis. Measure the absolute neutrophil count (ANC) before starting Ferriprox therapy and monitor it weekly while on therapy.
- Recommended management in the event of agranulocytosis or neutropenia during Ferriprox use is:
  - For agranulocytosis (ANC $<0.5 \times 10^9$/L):
  - Consider hospitalization and other management as clinically appropriate.
  - Do not resume Ferriprox in patients who have developed agranulocytosis unless potential benefits outweigh potential risks. Do not rechallenge patients who have developed neutropenia with Ferriprox unless potential benefits outweigh potential risks.
  - For neutropenia (ANC $<1.5 \times 10^9$/L and $>0.5 \times 10^9$/L):
  - Instruct the patient to immediately discontinue Ferriprox and all other medications with a potential to cause neutropenia.
  - Obtain a complete blood cell (CBC) count, including a white blood cell (WBC) count corrected for the presence of nucleated red blood cells, an absolute neutrophil count (ANC), and a platelet count daily until recovery (ANC $\geq 1.5 \times 10^9$/L).
- I agree to advise my patients:
  - To read the FDA-approved patient labeling (Medication Guide).
  - To store Ferriprox at 68°F to 77°F (20°C to 25°C); excursions permitted to 59°F to 86°F (15°C to 30°C) [see USP Controlled Room Temperature].
  - Ferriprox tablets (twice-a-day):
  - To take the first dose of Ferriprox tablets (twice-a-day) in the morning and the second in the evening.
  - To take Ferriprox tablets (twice-a-day) with food to reduce the risk of nausea and vomiting.
  - To avoid alcohol while taking Ferriprox tablets (twice-a-day). Consumption of alcohol while taking Ferriprox tablets (twice-a-day) may result in more rapid release of deferiprone.
  - Ferriprox tablets (three-times-a-day):
  - To store in the originally supplied bottle, closed tightly to protect from moisture. Advise patients to take the first dose of Ferriprox in the morning, the second dose at midday, and the third dose in the evening. Clinical experience suggests that taking Ferriprox with meals may reduce nausea.
  - If a dose of this medicine has been missed, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not catch up or double doses.
  - Inform patients of the risks of developing agranulocytosis and instruct them to immediately interrupt therapy and report to their physician if they experience any symptoms of infection such as fever, sore throat or flu-like symptoms.
  - Contact their physician in the event of overdose.
  - That their urine might show a reddish/brown discoloration due to the excretion of iron. This is a very common sign of the desired effect, and it is not harmful.
  - For pregnant women and females of reproductive potential, of the potential risk to a fetus. Advise females to inform their healthcare provider of a known or suspected pregnancy. Advise female patients of reproductive potential to use effective contraception during treatment with Ferriprox and for at least six months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with Ferriprox and for at least three months after the last dose.
  - That females should not breastfeed during treatment with Ferriprox and for at least 2 weeks after the last dose.

- I understand the following conditions under the Chiesi Total Care Program:
  - I will enroll myself in the Chiesi Total Care Program by completing this Prescriber Enrollment Form. I understand that I am to do this prior to my first patient being treated with Ferriprox.
  - I will enroll each patient by completing the Chiesi Total Care Program Intake Form at the time of enrollment. I understand that baseline data are only to be used to assess for risk factors for adverse events and to evaluate the long-term safety of Ferriprox.
  - I will notify the patient of the Chiesi Total Care Program and communicate the benefits and risks of Ferriprox therapy. Prior to initiation of Ferriprox therapy, a copy of the signed Patient Enrollment Form will be sent to the Chiesi Total Care Program, one copy will be given to the

patient whereas the original form will be kept with the patient's medical records.

- I will provide contraceptive counseling to women of childbearing potential while taking Ferriprox and ensure the interruption of therapy if they are trying to become pregnant or immediate interruption of therapy if they discover that they are pregnant while taking Ferriprox.
- I will notify the Chiesi Total Care Program when a patient discontinues Ferriprox. I will promptly report to Chiesi serious adverse events and specifically, any episodes of agranulocytosis, occurring in the course of the use of the drug.
- I understand that I am encouraged to report all suspected adverse reactions, as well as any cases of pregnancies, occurring in the course of the Ferriprox therapy.
- I understand that Chiesi, its agents, and contractors may contact me via phone, fax, mail, or e-mail to assess the effectiveness of the program requirements for the Chiesi Total Care Program, and/or to seek follow-up information for reported adverse experiences.

Prescribing Physician (Please Print): _____

Prescribing Physician Signature: _____ Date: _____/_____/_____

Please fax this completed form to Chiesi Total Care at 1-866-565-7794. You will receive enrollment confirmation via fax within 48 hours during standard business days. For questions regarding Chiesi Total Care call 1-866-758-7071.

Indication

Ferriprox® (deferiprone) is an iron chelator indicated for the treatment of transfusional iron overload due to:

- thalassemia syndromes
- sickle cell disease or other anemias

Ferriprox Tablets are indicated in adult and pediatric patients ≥8 years of age; Ferriprox Oral Solution is indicated in patients ≥3 years of age.

Limitations of Use

Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.

Important Safety Information

WARNING: AGRANULOCYTOSIS AND NEUTROPENIA

- **Ferriprox can cause agranulocytosis that can lead to serious infections and death. Neutropenia may precede the development of agranulocytosis.**
- **Measure the absolute neutrophil count (ANC) before starting Ferriprox and monitor weekly while on therapy.**
- **Interrupt Ferriprox if infection develops and monitor the ANC more frequently.**
- **Advise patients taking Ferriprox to report immediately any symptoms indicative of infection.**

Ferriprox is contraindicated in patients with known hypersensitivity to deferiprone or to any of the excipients in the formulations.

In pooled clinical trials, 7.5% of 642 patients with thalassemia syndromes treated with Ferriprox developed increased ALT values. Four (0.62%) Ferriprox-treated subjects discontinued the drug due to increased serum ALT levels and 1 (0.16%) due to an increase in both ALT and AST. In pooled clinical trials, 7.7% of 196 patients with sickle cell disease or other anemias treated with Ferriprox developed increased ALT values. Monitor serum ALT values monthly during therapy with Ferriprox and consider interruption of therapy if there is a persistent increase in the serum transaminase levels. Decreased plasma zinc concentrations have been observed on deferiprone therapy. Monitor plasma zinc, and supplement in the event of a deficiency.

Ferriprox can cause fetal harm. Advise females of reproductive potential to use an effective method of contraception during treatment with Ferriprox and for at least six months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with Ferriprox and for at least three months after the last dose. Advise females not to breastfeed during treatment with Ferriprox and for at least 2 weeks after the last dose.

Avoid co-administration of Ferriprox with other drugs known to be associated with neutropenia or agranulocytosis; however, if this is unavoidable, closely monitor the absolute neutrophil count. Avoid co-administration with UGT1A6 inhibitors. Allow at least a 4-hour interval between administration of Ferriprox and drugs or supplements containing polyvalent cations (e.g., iron, aluminum, or zinc).

The most common adverse reactions in patients with thalassemia (incidence ≥6%) are nausea, vomiting, abdominal pain, arthralgia, ALT increased and neutropenia. The most common adverse reactions in patients with sickle cell disease or other anemias (incidence ≥6%) are pyrexia, abdominal pain, bone pain, headache, vomiting, pain in extremity, sickle cell anemia with crisis, back pain, ALT increased, AST increased, arthralgia, oropharyngeal pain, nasopharyngitis, neutrophil count decreased, cough and nausea.

Inform patients that their urine might show a reddish/brown discoloration due to the excretion of the iron-deferiprone complex. This is a very common sign of the desired effect, and it is not harmful.

Advise patients to avoid alcohol while taking Ferriprox tablets (twice-a-day). Consumption of alcohol while taking Ferriprox tablets (twice-a-day) may result in more rapid release of deferiprone.

For full Prescribing Information, including boxed WARNING and Medication Guide, please click here.

Ferriprox® TWICE-A-DAY deferiprone 1000 mg tablets

Ferriprox® deferiprone
1000 mg tablets
500 mg tablets
Oral solution 100 mg/mL

PP-F-0029 V2.0 2021