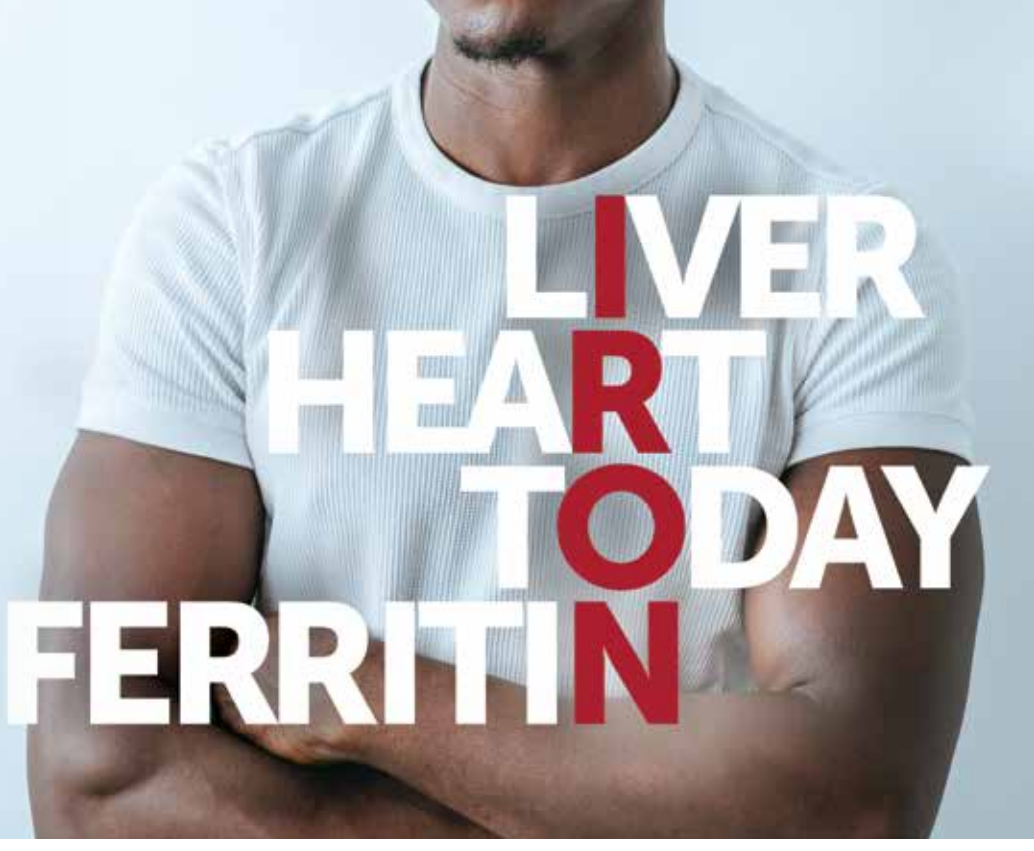
Tomorrow starts here



Ferriprox® TWICE-A-DAY deferiprone 1000 mg tablets

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

What is Ferriprox® (deferiprone)?

Ferriprox (deferiprone) is a prescription medicine used to treat iron overload from blood transfusions in people with:[1]

- thalassemia syndromes
- sickle cell disease or other anemias

Ferriprox Tablets are for adults and children ≥8 years of age; Ferriprox Oral Solution is for patients ≥3 years of age.

It is not known if Ferriprox is safe and effective to treat iron overload due to blood transfusions:

- in people with myelodysplastic syndrome or Diamond Blackfan anemia
- in children less than 3 years of age

What is the most important information I should know about Ferriprox?

Ferriprox can cause serious side effects, including a very low white blood cell count. One type of white blood cell that is important for fighting infections is called a neutrophil. If your neutrophil count is low (neutropenia), you may be at risk of developing a serious infection that can lead to death. Neutropenia is common with Ferriprox and can become severe in some people. Severe neutropenia is known as agranulocytosis. If you develop agranulocytosis, you will be at risk of developing serious infections that can lead to death.

Your healthcare provider should do a blood test before you start Ferriprox and weekly during treatment to check your neutrophil count. If you develop neutropenia, your healthcare provider should check your blood counts every day until your white blood cell count improves. Your healthcare provider may temporarily stop treatment with Ferriprox if you develop neutropenia or infection.

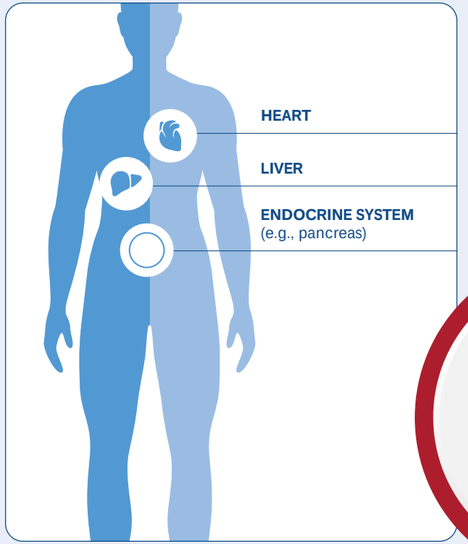
Stop taking Ferriprox and get medical help right away if you develop any of these symptoms of infection: fever, sore throat or mouth sores, flu-like symptoms, or chills and severe shaking.

Please see additional Important Safety Information, and the full Prescribing Information, including important WARNING and Medication Guide, in the back pocket.

OVERLOAD IRON

IRON OVERLOAD AFFECTS THE WHOLE BODY

Iron removal (chelation) is important for you if you receive repeated blood transfusions for the treatment of sickle cell disease[2]



Build-up of extra iron can damage the liver, heart, and endocrine system[3]

OVERLOAD IRON

IRON OVERLOAD IN SICKLE CELL DISEASE

Transfusional iron overload impacts outcomes associated with sickle cell disease[4,5]

As iron builds up in the body and organs, complications happen more often.[2]

A review of clinical trials from 2018 found that people with sickle cell disease with iron overload† had higher rates of:

DEATH
64%
compared to **5%** for those without iron overload[4†]

ORGAN FAILURE
71%
compared to **19%** for those without iron overload[4†]

PAIN EPISODES
64%
experienced ≥3 pain episodes per year compared to **38%** for those without iron overload[4†]

Another clinical study in 199 transfused people with sickle cell disease compared to 64 non-transfused people with sickle cell disease also showed an increase in the number of:

HOSPITAL STAYS
4.1
hospitalizations per year compared to 2.1 for non-transfused people ($p<0.001$)[5‡]

DEATHS
17
The death rate in adults with sickle cell disease who receive transfusions is 3 times higher than the general US population[5‡]

Iron chelation therapy is most beneficial when it is started early and taken as prescribed[4]

† Defined as serum ferritin levels >1,500 ng/mL and transferrin saturation >50%. Without iron overload was defined as serum ferritin levels <100 ng/mL and transferrin saturation <50%.[1]

‡ Based on a study of people who were either currently on or had received regular transfusion therapy and confirmed to have iron overload as defined by a liver iron concentration (LIC) of >10 mg/g dry weight (dw) or 3 serum ferritin values that averaged ≥2,000 ng/mL within the previous 12 months. 142 people with thalassemia and 199 people with sickle cell disease who received regular transfusions were included in the study group, and 64 people with sickle cell disease who did not receive transfusions were selected as controls.

MONITORING IRON IN SICKLE CELL DISEASE

Serum ferritin level and heart and liver iron should all be checked regularly[6]

Depending on the organ, it can take a long time to reduce iron – so treatment guidelines recommend preventing significant iron loading from the start.[2]

Find an MRI T2* facility near you with our online search tool

Target levels recommended by the American Society of Hematology (ASH) Guidelines and hematology experts[6]

	Sickle Cell Disease	
Parameter	Monitoring	Target
Serum ferritin	**ASH Guidelines recommend monthly serum ferritin tests[6]** Serum ferritin level should be checked at each transfusion, at least every month.[2]	**Serum ferritin µg/L[2]** Normal to acceptable level: 25-300 (green) Intermediate: 800-1,700 (orange) Very high: >2,500 (red)
	ACCEPTABLE — Lower number is better[2] — HIGH RISK 500 1,000	
Liver iron level	**ASH Guidelines recommend liver iron overload MRI T2* every 1 to 2 years** Liver iron overload should be checked by MRI§ every 1 to 2 years if you receive regular transfusions.[6]	**Liver iron level (MRI) mg/g dw[2]** Normal to acceptable level: 0.8-3.5 (green) Intermediate: 5.0-10.0 (orange) Very high: >20 (red)
	ACCEPTABLE — Lower number is better[2] — HIGH RISK 5 10	
Heart MRI T2*	**ASH Guidelines recommend heart MRI T2* if you have:[6]** • a high iron burden (liver iron level >15 mg/g/dw) for 2 years • signs of organ damage because of iron overload • or signs of heart problems	**Heart MRI T2* ms/s[2]** Normal: >30 Intermediate: 10-20 Very severe: <6
	HIGH RISK — Higher number is better[2] — ACCEPTABLE 10 20	

§ MRI=magnetic resonance imaging

KIDNEY FUNCTION AND SICKLE CELL DISEASE

Sickle cell disease (SCD) affects kidney structure and function, which leads to a condition called "sickle cell nephropathy"[7]

Sickle cell nephropathy is a major complication of sickle cell disease.[8]

Chronic kidney failure occurs in 4-20% of people with sickle cell disease who have a large amount of protein or nitrogen in the urine or blood.[8]

Kidney complications affect nearly

30-50%

of adults with sickle cell anemia[9]

Kidney effects of SCD account for

16-18%

of mortality in people with sickle cell disease[7]

Talk to your doctor to include kidney function monitoring as part of your ongoing healthcare management

IMPORTANT SAFETY

IMPORTANT SAFETY INFORMATION

What is Ferriprox® (deferiprone)

Ferriprox (deferiprone) is a prescription medicine used to treat iron overload from blood transfusions in people with:

- thalassemia syndromes
- sickle cell disease or other anemias

Ferriprox Tablets are for adults and children ≥8 years of age; Ferriprox Oral Solution is for patients ≥3 years of age.

It is not known if Ferriprox is safe and e□ective to treat iron overload due to blood transfusions:

- in people with myelodysplastic syndrome or Diamond Blackfan anemia
- in children less than 3 years of age

What is the most important information I should know about Ferriprox?

Ferriprox can cause serious side e□ects, including a very low white blood cell count. One type of white blood cell that is important for fighting infections is called a neutrophil. If your neutrophil count is low (neutropenia), you may be at risk of developing a serious infection that can lead to death. Neutropenia is common with Ferriprox and can become severe in some people. Severe neutropenia is known as agranulocytosis. If you develop agranulocytosis, you will be at risk of developing serious infections that can lead to death.

Your healthcare provider should do a blood test before you start Ferriprox and weekly during treatment to check your neutrophil count. If you develop neutropenia, your healthcare provider should check your blood counts every day until your white blood cell count improves. Your healthcare provider may temporarily stop treatment with Ferriprox if you develop neutropenia or infection.

Stop taking Ferriprox and get medical help right away if you develop any of these symptoms of infection: fever, sore throat or mouth sores, flu-like symptoms, or chills and severe shaking.

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IMPORTANT SAFETY

IMPORTANT SAFETY INFORMATION

Do not take Ferriprox® if you are allergic to deferiprone or any of the ingredients in Ferriprox.

See page 12 for a complete list of ingredients in Ferriprox.

Before you take Ferriprox, tell your healthcare provider about all of your medical conditions, including if you:

- Have liver problems
- Are pregnant or plan to become pregnant. Ferriprox can harm your unborn baby. You should avoid becoming pregnant during treatment with Ferriprox. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with Ferriprox.
- Are breastfeeding or plan to breastfeed. It is not known if Ferriprox passes into your breast milk. Do not breastfeed during treatment with Ferriprox and for at least 2 weeks after the last dose.

For females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with Ferriprox.
- You should use e□ective birth control during treatment with Ferriprox and for at least 6 months after the last dose.

For males with female partners who are able to become pregnant:

- You should use e□ective birth control during treatment with Ferriprox and for at least 3 months after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

MODE OF ACTION

Introducing Ferriprox®: An iron chelator shown to enter and remove toxic iron from organs and the bloodstream[1,10,11]

Ferriprox has been proven to reduce iron build-up especially in the heart – this e□cacy may be related to its high ability to enter heart cells.

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IRON REDUCTION IN SICKLE CELL DISEASE

Ferriprox® has been shown to provide effective liver iron reduction at 1 year with continuous reductions over 3 years[1]

Ferriprox was studied in a 1-year, controlled non-inferiority clinical trial of 185 people with sickle cell disease. 122 patients received Ferriprox over 1 year and 63 received deferoxamine.

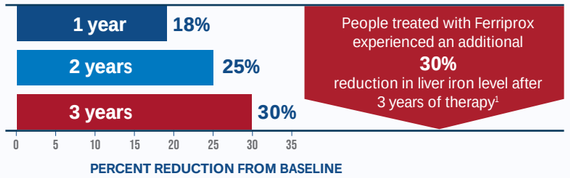
Reduction in liver iron level after 1 year of treatment with Ferriprox[1¶]

Effective liver iron reduction

In the clinical trial, the mean decrease in liver iron concentration (LIC) from baseline was -4.13 ± 0.50 mg/g dw after 1 year of treatment with Ferriprox compared to 4.38 ± 0.59 mg/g dw for deferoxamine.[1]

People who completed the 1-year study and enrolled in a 2-year extension study either continued to receive Ferriprox (n=89 people) or were switched to Ferriprox from deferoxamine (n=45 people).[1]

Reduction in liver iron level over 3 years of treatment with Ferriprox[1¶]



Continuous liver iron reduction

¶ Mean liver iron concentration value dropped from 14.93 mg/g dw at baseline.

The most common adverse reactions (≥6%) reported during clinical trials

The most common side e□ects of Ferriprox in people with sickle cell disease or other anemias include fever, stomach-area (abdominal) pain, bone pain, headache, vomiting, pain in arms or legs, sickle cell anemia with crisis, back pain, abnormal liver function tests, joint pain, mouth and throat pain, common cold, low white blood cells, cough and nausea.

TWICE-DAILY TABLETS

FERRIPROX® OFFERS A TWICE-DAILY FORMULATION[1]

Take Ferriprox with food to help reduce the risk of nausea and vomiting.[1]

Ferriprox 1000 mg Twice-A-Day tablets

Example:
Based on a 132 lb patient
@ highest recommended dose††

	75 mg/kg/day	99 mg/kg/day
MORNING		
EVENING		

INCREASE AS REQUIRED

†† Initial dose is 37.5 mg/kg to 49.5 mg/kg actual body weight, orally, twice daily with food for a total daily dose of 75 mg/kg to 99 mg/kg actual body weight.

IMPORTANT SAFETY INFORMATION

How should I take Ferriprox®?

- Take Ferriprox exactly as your healthcare provider tells you.
- Your healthcare provider will prescribe Ferriprox based on your body weight.
- Your healthcare provider will check your body iron level during treatment with Ferriprox and may change your dose if needed. Your healthcare provider may also change your dose of Ferriprox if you have certain side effects. Do not change your dose of Ferriprox unless your healthcare provider tells you to.
- There are 2 types of Ferriprox tablets that are taken on different schedules. Be sure you are taking the correct tablet and ask your healthcare provider if unsure.
  - **Ferriprox tablets (3 times a day):** Take this Ferriprox tablet 3 times each day. Take your first dose in the morning, the second dose at midday, and the third dose in the evening. Taking Ferriprox tablets with meals may help reduce nausea.
  - **Ferriprox tablets (2 times a day):** Take this Ferriprox tablet 2 times each day. Take your first dose in the morning and the second dose in the evening, about 12 hours apart. Taking Ferriprox tablets with meals may help reduce nausea.
- **If you must take a medicine to treat indigestion (antacid), or supplements that contain iron, aluminum, or zinc during treatment with Ferriprox, allow at least 4 hours between taking Ferriprox and these products.**
- If you take too much Ferriprox, call your healthcare provider.
- If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and then continue with your regular schedule. Do not try to catch up or take 2 doses at the same time to make up for a missed dose.

What should I avoid during treatment with Ferriprox?

- **Ferriprox tablets (2 times a day):** Avoid drinking alcohol during treatment with Ferriprox tablets (2 times a day). This may caxuse a faster release of the medicine.

What are the possible side effects of Ferriprox?

Ferriprox can cause serious side effects, including:

- **Increased liver enzyme levels in your blood.** Your healthcare provider should do monthly blood tests to check your liver function during treatment with Ferriprox.
- **Decreased levels of zinc in your blood.** Your healthcare provider will do blood tests to check your zinc levels during treatment with Ferriprox and may prescribe a zinc supplement for you if your zinc levels are low.

The most common side effects of Ferriprox in people with sickle cell disease or other anemias include:

- Fever
- Stomach-area (abdominal) pain
- Bone pain
- Headache
- Vomiting
- Pain in arms or legs
- Sickle cell anemia with crisis
- Back pain
- Abnormal liver function tests
- Joint pain
- Mouth and throat pain
- Common cold
- Low white blood cells
- Cough
- Nausea

Ferriprox may cause a change in urine color to reddish-brown. This is not harmful and is expected during treatment with Ferriprox.

These are not all of the possible side effects of Ferriprox.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see additional Important Safety Information, and the full Prescribing Information, including important WARNING and Medication Guide, in the back pocket.

Ferriprox® TWICE-A-DAY
deferiprone
1000 mg tablets

Ferriprox®
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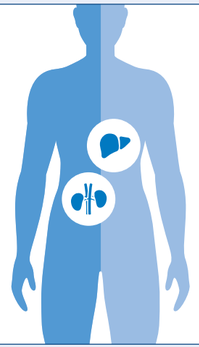

Ferriprox® is suitable for people with reduced kidney or liver‡‡ function[1]

‡‡ Ferriprox was not studied in patients with severely reduced liver function.

What are the ingredients in Ferriprox?

Active ingredient: deferiprone

Inactive ingredients:

- **Ferriprox tablets (three times a day):** Tablet core: methylcellulose, crospovidone, and magnesium stearate. Coating: hypromellose, hydroxypropyl cellulose, macrogol, and titanium dioxide.
- **Ferriprox tablets (twice a day):** Tablet core: hypromellose acetate succinate, magnesium oxide, colloidal silicon dioxide and magnesium stearate. Coating: triethyl citrate, talc, titanium dioxide, and methacrylic acid and ethyl acrylate copolymer.

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Ferriprox® TWICE-A-DAY deferiprone 1000 mg tablets

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1000 mg tablets
500 mg tablets
Oral solution 100 mg/mL

How should I store Ferriprox®?

- Store Ferriprox at room temperature between 68°F to 77°F (20°C to 25°C).
- Store Ferriprox tablets (3 times a day) in the original bottle and tightly closed to protect from moisture.

Keep Ferriprox and all medicines out of the reach of children.

General information about the safe and effective use of Ferriprox.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Ferriprox for a condition for which it was not prescribed. Do not give Ferriprox to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Ferriprox that is written for health professionals.

Established safety profile

Ferriprox can cause serious side e□ects, including a very low white blood cell count (neutropenia).

Severe neutropenia is known as agranulocytosis.

- In clinical studies agranulocytosis occurred in 1.5% of people with sickle cell disease.[1]

If you develop a fever, a sore throat or mouth sores, flu-like symptoms, or chills and severe shaking, follow the 3 steps below:[1]

1

Stop the drug immediately

2

Seek medical attention immediately
(i.e., go to the ER or your doctor for blood monitoring)

3

Notify the ER provider or your doctor
that you are taking a medication that can cause agranulocytosis

ONE-STOP SUPPORT

ONE-STOP PATIENT SUPPORT

A single call to your dedicated Chiesi Total Care℠ team is all it takes and you'll receive:

Individual support
from your Patient Service Coordinator to understand your medication and your medical needs

Insurance assistance
so that you receive what you qualify for

Worry-free refills
A pharmacist is always available and medication is delivered right to your door

The Ferriprox® Copay Program§§

You may pay as little as $0 for your prescription.

Program eligibility:
- You are enrolled in Chiesi Total Care. (Enrollment and Authorization form is mailed to your home.)
- You have commercial insurance and a valid prescription for a US Food and Drug Administration (FDA)-approved indication for Ferriprox.
- You are a resident of the United States or one of its territories.

§§ Please refer to the full Terms and Conditions in the back pocket for additional eligibility requirements.

The most common side effects of Ferriprox in people with sickle cell disease or other anemias include:

- Fever
- Stomach-area (abdominal) pain
- Bone pain
- Headache
- Vomiting
- Pain in arms or legs
- Sickle cell anemia with crisis
- Back pain
- Abnormal liver function tests
- Joint pain
- Mouth and throat pain
- Common cold
- Low white blood cells
- Cough
- Nausea

Ferriprox may cause a change in urine color to reddish-brown. This is not harmful and is expected during treatment with Ferriprox.

These are not all of the possible side effects of Ferriprox.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Lesa, Chiesi Total Care Pharmacist

ADDITIONAL RESOURCES

These organizations and online communities provide valuable tools, information, and support for you and your family

Centers for Disease Control and Prevention – Sickle Cell Disease
cdc.gov/ncbddd/sicklecell

Centers for Disease Control and Prevention – Real stories from people living with sickle cell disease
cdc.gov/ncbddd/sicklecell/stories

Sickle Cell Disease Association of America (SCDAA)
sicklecelldisease.org

Sickle Cell Consortium
sicklecellconsortium.org

Sickle Cell 101
sc101.org

References: 1. Ferriprox® (deferiprone) Prescribing Information. Chiesi, April 2021. **2.** Coates TD, Wood JC. How we manage iron overload in sickle cell patients. *Br J Haematol* 2017;177(5):703-716. **3.** Hider RC, Ho□brand AV. The role of deferiprone in iron chelation. *N Engl J Med* 2018;379:2140-2150. **4.** Ballas SK, et al. The e□ect of iron chelation therapy on overall survival in sickle cell disease and ß-thalassemia: a systematic review. *Am J Hematol* 2018;93:943-952. **5.** Fung EB, et al. Morbidity and mortality in chronically transfused subjects with thalassemia and sickle cell disease: a report from the multi-center study of iron overload. *Am J Hematol* 2007;82:255-265. **6.** Chou ST, et al. American Society of Hematology 2020 guidelines for sickle cell disease: transfusion support. *Blood* 2020;4(2):327-355. **7.** Nath KA, Hebbel RP. Sickle cell disease: renal manifestations and mechanisms. *Nat Rev Nephrol* 2015;11(3):1171-1171. **8.** Evidence-based management of sickle cell disease: expert panel report, 2014. National Heart Lung and Blood Institute. Accessed online January 13, 2021 at https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease. **9.** Sundaram N, Bennett M, Wilhelm J, et al. Biomarkers for early detection of sickle nephropathy. *Am J Hematol* 2011;86(7):559-566. **10.** Jamuar SS, Lai AHM. Safety and e□cacy of iron chelation therapy with deferiprone in people with transfusion-dependent thalassemia. *Ther Adv Hematol* 2012;3(5):299-307. **11.** Lin CH, et al. Therapeutic mechanism of combined oral chelation therapy to maximize e□cacy of iron removal in transfusion-dependent thalassemia major – a pilot study. *Expert Rev Hematol* 2019;12(4):265-272.

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High ability to enter organ cells

Ferriprox® has been shown to enter and remove toxic iron from organs and the bloodstream.[1,10,11]

Effective iron reduction

Ferriprox has been shown to provide e□ective liver iron reduction at 1 year (-4.13 ± 0.50 mg/g dw) with continuous reductions over 3 years (up to 30%¶¶).

¶¶ LIC dropped from 14.93 mg/g dw at baseline to 10.45 mg/g dw after 3 years of treatment.[1]

Expanded formulations

- **Ferriprox o□ers a twice-a-day formulation**
- Suitable for people with reduced kidney or liver††† function.[1]

Exceptional support

- The Ferriprox Copay Program – people may pay as little as $0 if eligible.‡‡‡

††† Ferriprox was not studied in people with severely reduced liver function.
‡‡‡ Please refer to the full Terms and Conditions in the back pocket for additional eligibility requirements.

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It is not known if Ferriprox is safe and e□ective to treat iron overload due to blood transfusions:
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Stop taking Ferriprox and get medical help right away if you develop any of these symptoms of infection: fever, sore throat or mouth sores, flu-like symptoms, or chills and severe shaking.

For more information, visit ferriprox.com.

PP-F-0117 V2.0 2021

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