

FERRIPROX[®]

Deferiprone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ferriprox. It does not contain all of the available information. Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your taking Ferriprox against the benefits they expect it will have for you.

If you have any concerns about taking Ferriprox, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

What Ferriprox is used for

Ferriprox contains a medicine called deferiprone which is used for the treatment of iron overload in patients with thalassaemia major unable to take desferrioxamine or in whom desferrioxamine has proven ineffective.

Deferiprone is a medicine that removes iron from the body.

In a disease such as “thalassaemia”, there is accumulation of iron in the body in those patients who are dependent on blood transfusions. If not removed, the iron levels can reach a serious level in the body as a result of the accumulation. By removing the excess iron from the body, Ferriprox can reduce the serious effects of iron overload.

Ask your doctor if you have any questions about why Ferriprox has been prescribed for you. Your doctor may have prescribed it for another use.

Ferriprox is not addictive.

Ferriprox is only available on a doctor's prescription.

Before you take Ferriprox

When you must not take it

Do not take Ferriprox if you or your child:

- have a history of hypersensitivity (an allergy) to the active substance or any of the other ingredients listed at the end of this leaflet. Signs of allergic reactions may include itchy skin, rash, shortness of breath and swelling of the face or tongue.

- have a history of repeated episodes of neutropenia (low white blood cell count)
- have a history of agranulocytosis (very low white blood cell count $<0.5 \times 10^9/L$)
- are currently taking medicines known to cause neutropenia
- are pregnant or breast-feeding.

Your doctor can advise you on the medicines that can cause neutropenia or agranulocytosis.

Tell your doctor if you are pregnant or intend to become pregnant or breast-feeding. Do not take this medication if you are breast-feeding, if you are pregnant, or if you are trying to become pregnant. This medication could seriously harm your baby. You must use effective contraception while you are taking deferiprone. Ask your doctor which method is best for you. If you become pregnant while taking deferiprone, stop taking the medicine immediately and tell your doctor.

Do not take Ferriprox if the packaging is torn or seems to have been opened.

Do not take Ferriprox after the expiry date printed on the bottle.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have any of the following medical conditions:

- hepatitis
- HIV
- liver or kidney disease
- problems with your immune system

Taking other medicines

Tell your doctor or pharmacist about all other medicines that you are taking, even ones that you can buy without a prescription.

Do not take vitamin C or antacids containing aluminium at the same time as Ferriprox.

Your doctor can tell you which medicines you can safely take with Ferriprox.

How to take Ferriprox

It is important to follow the directions that your doctor has given to you.

How much to take

How much of Ferriprox that you take will depend on your weight. The usual dose of Ferriprox is three (3) times per day.

Do not take more than the dose your doctor has recommended.

When to take it

Take your first dose in the morning. Take your second dose midday. Take your third dose in the evening.

You do not have to take this medicine with food. However, you may find it easier to remember to take your medicine, if you take it with your meals. If you experience nausea or vomiting, it may help to take your deferiprone with some food.

Do not take antacids containing aluminium at the same time as Ferriprox.

Take your Ferriprox the same time each day. This will help you remember when to take the medicine.

How long to take it

Do not stop taking Ferriprox unless your doctor tells you to. If Ferriprox has been successfully reducing the levels of iron in your body, stopping Ferriprox will cause the iron levels in your body to rise again, so that the risk of problems with excess body iron may return.

If you forget to take it

Ferriprox will be most effective if you do not miss any doses.

If you forget to take a dose of Ferriprox, leave out that dose completely. Take your next dose at the normal time it is due.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take it, ask your pharmacist for some hints.

If you take too much (overdose)

Telephone your doctor or Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Ferriprox even if there are no signs of discomfort or poisoning.

While you are taking Ferriprox

Things you must do

Make sure that all of your doctors and pharmacists know about your use of Ferriprox. Remind them if any new medicines are about to be started.

Things you must not do

Be sure to keep all of your doctor's appointments so your progress can be checked. Your doctor will ask you to come in for tests to monitor body iron load. As a precaution, your

doctor may have your blood, liver and kidney tested regularly during treatment with Ferriprox. Some blood tests may be done as often as once a week to avoid side effects.

In addition, he or she also might ask you to undergo liver biopsies.

Do not use Ferriprox to treat any complaint other than that directed by your doctor. It may not be safe to use Ferriprox for another complaint.

Do not give Ferriprox to someone else even if their symptoms are the same. It may not be safe for another person to use Ferriprox.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how this medicine affects you.

Ferriprox should not affect your ability to drive or use machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you feel unwell while you are taking Ferriprox. Like all medicines, Ferriprox may have some side effects. Most side effects are mild and patients often find that these wear off after a few weeks.

Your urine may become a reddish/brown colour. This is the most common undesirable effect of deferiprone and it is not harmful.

Tell your doctor immediately if you notice any symptoms of infection such as fever, sore throat or flu-like symptoms.

The most serious side effect of deferiprone is the occurrence of a very low white blood cell count. This condition, known as severe neutropenia or agranulocytosis, has occurred in about 1.0% of people who have taken deferiprone in clinical studies. Because white blood cells help to fight infection, a low white blood cell count may place you at risk of developing a serious infection. If an infection of this nature is not discovered and treated early, it could cause death.

Tell your doctor or pharmacist if you notice any of the following that are troublesome or ongoing:

- joint pain and swelling
- abdominal pain
- diarrhoea
- nausea
- vomiting
- increase in appetite.

These effects generally disappear after a few days to a few weeks of continued treatment.

If these events persist, you should consult your doctor.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell. Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Ferriprox

Storage

- Do not store it or any other medicine in the bathroom or near a sink.
- Do not leave it in the car on hot or cold days. Heat, cold and dampness can destroy some medicines.
- Keep Ferriprox where children cannot reach it. A locked cupboard at least one- and-a-half metre above the ground is a good place to store medicines.
- Keep Ferriprox in the bottle until it is time to take your dose. If it is removed from the bottle, it may not keep well.
- After opening, keep Ferriprox oral solution protected from light in a place where the temperature stays below 2°C - 8°C (refrigerate – do not freeze).
- After opening use within 35 days.

Disposal

Return any unused medicine to your pharmacist.

Product description

What Ferriprox looks like

Ferriprox oral solution is a clear, reddish-orange coloured liquid.

Ingredients

Ferriprox oral solution contains 100 mg/mL of the active ingredient, deferiprone. It also contains the following inactive ingredients:

- Purified water
- Hydroxyethyl cellulose
- Glycerol
- Hydrochloric acid
- Artificial cherry flavour
- Peppermint oil
- Sunset yellow FCF
- Sucralose

Ferriprox oral solution is available in plastic bottles containing 250 mL or 500 mL. Each pack of Ferriprox oral solution will contain one bottle and one graduated plastic dosing cup.

Manufacturer/Supplier

Ferriprox is made in Canada by Apotex Inc., and is supplied in Australia by:

Orphan Australia Pty. Ltd.
48 Kangan Drive
Berwick
Victoria 3806
www.orphan.com.au

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Australian Registration Numbers:
500 mg tablets: AUST R 93946
25 g/250 mL oral solution: AUST R 125665
50 g/500 mL oral solution AUST R 125666

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