

FERRIPROX[®]

Active ingredient: *deferiprone*

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking FERRIPROX?

FERRIPROX contains the active ingredient deferiprone. FERRIPROX is used in adults and children over 1 year old for the treatment of iron overload in patients with thalassaemia major who are unable to take desferrioxamine or in whom desferrioxamine therapy has proven ineffective.

For more information, see Section [1. Why am I taking FERRIPROX?](#) in the full CMI.

2. What should I know before I take FERRIPROX?

Do not use if you have had an allergic or hypersensitivity reaction to deferiprone in the past, or any of the ingredients listed at the end of the CMI.

Do not use if you have a history of repeated episodes of neutropenia (low white blood cell count) or a history of agranulocytosis (very low white blood cell count $<0.5 \times 10^9/L$).

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take FERRIPROX?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor about any other medicines you are taking. Some medicines and FERRIPROX may interfere with each other or make you more likely to get side effects.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take FERRIPROX?

Your doctor will tell you how much to take. The usual dose is three times a day, with or without food.

More instructions can be found in Section [4. How do I use FERRIPROX?](#) in the full CMI.

5. What should I know while taking FERRIPROX?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are taking FERRIPROX.Go to all of your appointments and get all of the tests so that your doctor can monitor your progress and check for any effects on your health.Take adequate contraception to avoid becoming pregnant and stop taking FERRIPROX and tell your doctor immediately if you do become pregnant.
Things you must not do	<ul style="list-style-type: none">Do not change the amount or suddenly stop taking FERRIPROX without speaking to your doctor.
Driving or using machines	FERRIPROX should not affect your ability to drive or use machinery. However, be careful driving, operating machinery or doing jobs that require you to be alert until you know how this medicine affects you.
Looking after your medicine	<ul style="list-style-type: none">500 mg tablets: Store below 25°C.1,000 mg tablets: Store below 30°C. Keep the bottle tightly closed to protect from moisture. Use within 50 days of first opening.For more details see Section 7. Product Details in the full CMI.

For more information, see Section [5. What should I know while taking FERRIPROX?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary.

Less serious side effects include joint pain and swelling, abdominal pain, diarrhoea, nausea, vomiting, increase in appetite, headache, and change in colour of your urine to reddish/brown.

Serious side effects that need you to tell your doctor about immediately include symptoms of an infection such as fever, sore throat, flu-like symptoms); allergic symptoms (such as rash, itching, hives on the skin, swelling of the face, lips, tongue or other parts of the body); problems with your heart such as fast, slow or irregular heartbeat.

For more details and the complete list of possible side effects and what to do, see Section [6. Are there any side effects?](#) in the full CMI.

FERRIPROX[®]

Active ingredient: *deferiprone*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking FERRIPROX. **Speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FERRIPROX.**

Where to find information in this leaflet:

- [1. Why am I taking FERRIPROX?](#)
- [2. What should I know before I take FERRIPROX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take FERRIPROX?](#)
- [5. What should I know while taking FERRIPROX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking FERRIPROX?

FERRIPROX contains the active ingredient *deferiprone*. Ferriprox is a medicine that removes iron from the body.

FERRIPROX is used in adults and children over 1 year old is used for the treatment of iron overload in patients with thalassaemia major who are unable to take desferrioxamine or in whom desferrioxamine therapy has proven ineffective.

In a disease such as thalassaemia major, 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.

2. What should I know before I take FERRIPROX?

Warnings

Do not take FERRIPROX if you:

- are allergic to *deferiprone* or any of the ingredients listed at the end of this leaflet
- have a history of repeated episodes of neutropenia (low white blood cell count)
- have a history of agranulocytosis (a very low white blood cell count $<0.5 \times 10^9/L$)

Always check the ingredients to make sure you can take this medicine.

Check with your doctor if:

- You have or have had any of the following medical conditions:
 - liver problems including hepatitis.
 - kidney problems.
 - heart problems, low potassium or low magnesium levels.
 - HIV or other medical conditions where your immune system is compromised.
- You take any medicines for anything else.

While taking FERRIPROX, you may be at risk of getting certain side effects. It is important you understand these risks and how to watch for them. See extra information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not take FERRIPROX 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 FERRIPROX.

Do not take FERRIPROX if you are breast-feeding. It is not known if this medicine passes into breastmilk.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Other medicines and FERRIPROX may interfere with each other, affect the way they all work and/or increase the risk of side effects. These include:

- medicines that have the effect of lowering your blood white cell count, which could make you more likely to get an infection
- antacids (medicines that relieve heartburn and indigestion) that contain aluminium as an ingredient
- Vitamin C

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these interfere with FERRIPROX.

4. How do I take FERRIPROX?

How much to take

Your doctor (specialist) will tell you how much to take. It depends on your blood tests and your body weight.

The usual dose of FERRIPROX is three (3) times per day .

When to take FERRIPROX

Take your first dose in the morning. Take your second dose at midday. Take your third dose in the evening. Take it at about the same time every day.

You can take it with or without food, but it may help to take it with meals to help you remember to take it, or if you have nausea or vomiting (feeling or being sick).

How to take FERRIPROX

FERRIPROX tablets should be swallowed whole with a glass of liquid.

If you forget to take FERRIPROX

If you miss your dose at the usual time, skip the dose you missed and take your next dose when you are meant to.

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

If you take too much FERRIPROX

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26) in Australia, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking FERRIPROX?

Things you should do

- Keep your appointments with your doctor.
- Have all tests recommended by your doctor, to monitor your progress and manage any side effects. These may include tests on your blood, liver and kidney.
- Take any supplements that your doctor recommends.
- Make sure you always use sunscreen when taking FERRIPROX, as it can make your skin more likely to react to the sun- i.e., sunburn, rash.
- Remind any doctor, dentist or pharmacist you visit that you are taking FERRIPROX, especially if they are giving you a new medicine to take, or if you are having any other blood tests, as FERRIPROX can interfere with some tests.

Stop taking FERRIPROX and call your doctor straight away if:

- you become pregnant or plan to become pregnant.
- you get symptoms of an infection (fever, sore throat, flu-like symptoms)

Things you must not do

- Do not change the dosage or stop taking FERRIPROX unless your doctor tells you to.
- Do not take FERRIPROX to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

FERRIPROX is unlikely to affect your alertness but be careful before you drive or use any machines or tools until you know how FERRIPROX affects you.

Drinking alcohol

It is not known if alcohol affects how FERRIPROX works or if you are more likely to get side effects.

Looking after FERRIPROX

Storage instructions:

Keep your medicine in its original container until it is time to take your dose.

- **500 mg tablets:** Store below 25°C.
- **1,000 mg tablets:** Store below 30°C. Keep the bottle tightly closed to protect from moisture. Use within 50 days of first opening.

Store all medicines in a cool dry place away from moisture, heat or sunlight; for example, do not store them:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep them where young children cannot see or reach them.

When to discard your medicine

Discard your medicine if:

- your doctor or pharmacist tells you to stop taking this medicine
- the expiry date has passed
- the packaging is torn or shows signs of tampering

Getting rid of any unwanted medicine

Take it to any pharmacy where it will be disposed of safely.

6. Are there any side effects?

All medicines can have side effects. If you do have any side effects, most of them will be minor and short-lived. However, some side effects may need medical attention.

See the information below and ask your doctor or pharmacist if you have any questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Bone, muscle and tissues</p> <ul style="list-style-type: none"> joint pain and swelling <p>Digestive system</p> <ul style="list-style-type: none"> feeling or being sick (nausea or vomiting) stomach pain or burning or bloating (indigestion) diarrhoea increased or decreased appetite <p>Kidney</p> <ul style="list-style-type: none"> changes in urine colour to red-brown or other unusual urine colour <p>Nervous system</p> <ul style="list-style-type: none"> headache 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>General body</p> <ul style="list-style-type: none"> symptoms of an infection (fever, sore throat, flu-like symptoms) <p>Hypersensitivity (allergic) reaction:</p> <ul style="list-style-type: none"> may include rash, itching or hives on the skin, skin redness swollen face, lips, eyes, tongue or throat or other parts of the body <p>Heart</p> <ul style="list-style-type: none"> fast, slow or irregular heartbeat (arrhythmia) 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed may occur in some people.

Always speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects in Australia to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

7. Product details

This medicine is only available with a doctor's prescription.

What FERRIPROX contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> deferiprone
Other ingredients (inactive ingredients)	<p>500 mg film-coated tablets</p> <ul style="list-style-type: none"> magnesium stearate hypromellose microcrystalline cellulose silicon dioxide macrogol 3350 titanium dioxide
	<p>1,000 mg tablets</p> <ul style="list-style-type: none"> magnesium stearate hypromellose methylcellulose crospovidone hypollose macrogol 8000 titanium dioxide

Do not take this medicine if you are allergic to any of these ingredients.

What FERRIPROX looks like

500 mg tablets: White to off-white, capsule shaped, film coated, scored, printed "APO [bisect] 500" on one side and plain on the other side. The tablets can be broken in half.

They are packed in HDPE bottles with child-resistant caps, containing 100 tablets.

1,000 mg tablets: White to off-white, capsule shaped, film coated, scored, printed "APO [bisect] 1000" on one side and plain on the other side. The tablets can be broken in half.

They are packed in HDPE bottles with child-resistant caps, containing 50 tablets.

Not all strengths may be available.

ARTG Numbers:

Ferriprox 500 mg tablets: AUST R 93946

Ferriprox 1,000 mg tablets: AUST R 280204

Who distributes FERRIPROX

Chiesi Australia Pty Ltd
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