

FERRIPROX®

Deferiprone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FERRIPROX film-coated tablets. 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 tablets against the benefits they expect they will have for you.

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

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

What FERRIPROX tablets are used for

FERRIPROX tablets contain 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 toxic level in the body as a result of the accumulation. By removing the excess iron from the body, FERRIPROX can reduce the toxic effects of iron overload.

Your doctor may have prescribed FERRIPROX tablets for another use. Ask your doctor if you have any questions about why FERRIPROX tablets have been prescribed for you.

FERRIPROX tablets are not addictive.

FERRIPROX tablets are only available on a doctor's prescription.

Before you take FERRIPROX

FERRIPROX tablets are not suitable for everyone.

Do not take FERRIPROX if:

- you have a history of hypersensitivity (an allergy) to the active substance or any of the other ingredients (see below)
- you have a history of repeated episodes of neutropenia (low white blood cell count)
- you have a history of agranulocytosis (very low white blood cell count $<0.5 \times 10^9/L$)
- you are currently taking medication known to cause neutropenia
- you are pregnant or breast-feeding.

The way deferiprone causes neutropenia is not known. Do not take FERRIPROX with other medicinal products known to be associated with neutropenia or those which can cause agranulocytosis.

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

Do not take FERRIPROX tablets after the expiry date printed on the bottle.

Before you start to use it

Tell your doctor if you have any allergies.

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.

Tell your doctor about all other medications that you are taking, even ones that you can buy without a prescription. Your doctor can tell you which medications you can safely take with FERRIPROX.

How to take FERRIPROX tablets

Do not take FERRIPROX tablets to treat any condition other than that directed by your doctor.

How much to take

It is important to follow the directions that your doctor has given to you. How much of FERRIPROX that you take will depend on your weight. FERRIPROX is usually prescribed to be taken 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. It is not necessary to take FERRIPROX with food. However, you may find it easier to remember to take your medication, if you take it with your meals.

Food reduces the absorption of FERRIPROX slightly, but this does not have any effect on the overall ability of FERRIPROX to remove iron.

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

How long to take it

You should not normally stop taking FERRIPROX tablets unless your doctor tells you to. If FERRIPROX tablets have been successfully reducing the levels of iron in your body, stopping FERRIPROX tablets 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 feel unwell during your course of treatment, tell your doctor.

If you forget to take FERRIPROX tablets

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

If you forget to take a dose of FERRIPROX tablets, 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.

Do not change your daily dose without first talking to your doctor.

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

If you have taken too many FERRIPROX tablets

Telephone your doctor or go to casualty at your nearest hospital immediately if you think that you or anyone else may have taken too many FERRIPROX tablets even if

there are no signs of discomfort or poisoning.

While you are taking FERRIPROX tablets

FERRIPROX should not affect your ability to drive or operate machinery.

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.

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

Patients with iron overload are at increased risk of cancer. In these circumstances the impact of FERRIPROX is not known.

Things you must do

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

Things that you must not do

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

FERRIPROX tablets should only be used by the person for whom it was prescribed. Do not give FERRIPROX tablets to someone else even if their symptoms are the same. It may not be safe for another person to use FERRIPROX tablets.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FERRIPROX tablets. Like all medicines, FERRIPROX tablets may have some side effects. Most side effects are mild

and patients often find that these wear off after a few weeks.

More serious side effects

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. Your doctor will ask you to have a blood test (to check your white blood cell count) regularly, as frequently as every week. It is very important for you to keep all of these appointments. Report immediately to your doctor any symptoms of infection such as fever, sore throat or flu-like symptoms.

Less serious side effects

Less serious side effects include:

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

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

If you experience nausea or vomiting, it may help to take your deferiprone with some food.

If these events persist, you should consult your doctor.

Your urine may become a reddish/brown colour. This is the most common

undesirable effect of deferiprone and it is not harmful.

Other side effects not listed above may also occur in some patients.

If you notice any side effects, please inform your doctor or pharmacist.

After using FERRIPROX tablets

Storage

- Keep FERRIPROX tablets in their bottle until it is time to take your dose. If you take them out of their container, they may not keep well.
- Keep FERRIPROX tablets in a cool dry place where the temperature stays below 25°C.
- 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 tablets 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.

Disposal

Return any unused medicine to your pharmacist.

Product description

What FERRIPROX tablets look like

FERRIPROX tablets 500 mg are white, capsule-shaped, film-coated and imprinted "APO" bisect "500" on one side, plain on the other. The tablet is scored and breakable in half.

Ingredients

Each FERRIPROX tablet contains 500 mg of the active ingredient, Deferiprone.

FERRIPROX tablets also contain the following inactive ingredients:

Microcrystalline cellulose
Magnesium stearate
Silicon dioxide
Hypromellose
Macrogol
Titanium dioxide

FERRIPROX tablets are available in plastic bottles containing 100 tablets.

Manufacturer/Supplier

FERRIPROX tablets are made in Canada by TorPharm, Inc. for Apotex Inc., and are supplied in Australia by:

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

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