

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

SIROXTRIN 125 dispersible tablets

SIROXTRIN 250 dispersible tablets

SIROXTRIN 500 dispersible tablets

Deferasirox

Contains sugar (lactose monohydrate)

SIROXTRIN 125 contains lactose monohydrate 76,950 mg per dispersible tablet.

SIROXTRIN 250 contains lactose monohydrate 153,900 mg per dispersible tablet.

SIROXTRIN 500 contains lactose monohydrate 307,800 mg per dispersible tablet.

Read all of this leaflet carefully before you start taking SIROXTRIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SIROXTRIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SIROXTRIN is and what it is used for
2. What you need to know before you take use SIROXTRIN
3. How to take SIROXTRIN



4. Possible side effects
5. How to store SIROXTRIN
6. Contents of the pack and other information

1. What SIROXTRIN is and what it is used for

SIROXTRIN contains an active substance called deferasirox an iron chelator used to remove the excess iron from the body tissues.

SIROXTRIN is used for:

- Transfusional iron overload (excess amount of iron in patients receiving regular blood transfusions) SIROXTRIN is used to treat iron overload caused by blood transfusions.
- Non-transfusion-dependent thalassaemia syndromes (excess amount of iron in patients with thalassaemia not receiving regular blood transfusions).

2. What you need to know before you take SIROXTRIN

Do not take SIROXTRIN:

- If you are hypersensitive (allergic) to deferasirox or any of the other ingredients of SIROXTRIN (listed in section 6).
- If you have any kidney problems.
- If you are using a medicine called repaglinide that is used to control high blood sugar.
- If you have high risk myelodysplastic syndrome (MDS).
- If you have other blood disorders.
- If you have a severe liver disease.
- If you are pregnant or breastfeeding.



Warnings and precautions

Take special care with SIROXTRIN:

If any of the following applies to you, tell your doctor, pharmacist or healthcare provider before taking SIROXTRIN:

- Extra caution should be used in elderly patients as they may experience side effects more frequently.
- If you have a kidney or a liver problem.
- If you vomit blood and/or have black stools.
- If you are taking anti-inflammatory medicines (NSAIDs) as it may increase the risk of gastrointestinal complications.
- If you develop a severe rash, or difficulty breathing and dizziness or swelling mainly of the face and throat (signs of severe allergic reaction, see section 4).
- If you experience a combination of any of the following symptoms: rash, red skin, blistering of the lips, eyes, or mouth, skin peeling, high fever, flu-like symptoms, enlarged lymph nodes (signs of severe skin reaction, see section 4).
- If you have blurred vision or your hearing is decreasing.
- If you have a low level of platelets or white blood cells in your blood test.
- Blood tests to monitor the amount of ferritin should be done regularly.
- If you have a heart problem due to iron overload.

Children and adolescents

SIROXTRIN can be used to treat adolescents and children aged 2 years and over for chronic iron overload due to blood transfusions and 10 years and over for chronic iron overload with non-transfusion-dependent thalassemia syndromes. The dose of SIROXTRIN is related to body weight for all patients. Your doctor will tell you how many tablets to take.



Other medicines and SIROXTRIN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

This includes in particular:

- Antacids (medicines used to treat heartburn) containing aluminium should not be taken at the same time as SIROXTRIN.
- Anti-inflammatory (NSAIDs) medicines may increase the risk of gastrointestinal complications.
- Ciclosporin (used to prevent the body rejecting a transplanted organ), simvastatin (used to lower cholesterol) and birth control medicines.
- Rifampicin (used to treat tuberculosis), phenytoin, phenobarbital, carbamazepine (used to treat epilepsy) and ritonavir (used in the treatment of HIV infection).
- Repaglinide (used to control high blood sugar) and paclitaxel (used in cancer treatment).
- Theophylline (used to treat respiratory diseases such as asthma).
- Busulfan (used in cancer treatment).

SIROXTRIN with food and drink

SIROXTRIN must be taken on an empty stomach at least 30 minutes before eating any food preferably at the same time each day. SIROXTRIN tablets must be dispersed in water, apple or orange juice. For more information, see section 3 “How to take SIROXTRIN”.

Do not dissolve tablets in fizzy drinks or milk.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.



Pregnancy

SIROXTRIN should not be used during pregnancy.

Breastfeeding

Do not take SIROXTRIN if you are breastfeeding your baby.

Fertility

The effect of SIROXTRIN on human fertility is not known.

Driving and using machines

It is not always possible to predict to what extent SIROXTRIN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SIROXTRIN affects them.

If you feel dizzy after taking SIROXTRIN, do not drive or operate any tools or machines until you are feeling normal again.

SIROXTRIN contains lactose

SIROXTRIN contains lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take SIROXTRIN.

SIROXTRIN contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take SIROXTRIN

Do not share medicines prescribed for you with any other person.

Always take SIROXTRIN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.



How much SIROXTRIN to take

- SIROXTRIN can be used to treat adults, adolescents and children aged 2 years and over. The dose of SIROXTRIN is related to body weight for all patients. Your doctor will tell you how many tablets to take.
- The usual daily dose of SIROXTRIN at the start of the treatment is 20 mg per kilogram body weight for patients receiving regular blood transfusions.
- 10 mg per kilogram body weight for patients not receiving regular blood transfusions.
- A higher or lower starting dose may be recommended by your doctor based on your individual treatment needs. Depending on how you respond to treatment, your doctor may later adjust your treatment to a higher or lower dose.
- The maximum recommended daily dose is:
 - 40 mg per kilogram body weight for patients receiving regular blood transfusions.
 - 20 mg per kilogram body weight for patients not receiving regular blood transfusions.

Take SIROXTRIN

- Once a day, every day, at about the same time each day.
- On an empty stomach at least 30 minutes before eating any food.
- Disperse the tablets completely by stirring in a glass of water, apple or orange juice until a suspension forms. Drink the entire contents of the glass, then add a little water or juice to what is left in the empty glass and drink that too.

Your doctor will tell you how long your treatment with SIROXTRIN will last.

If you have the impression that the effect of SIROXTRIN is too strong or too weak, tell your doctor or pharmacist.



If you take more SIROXTRIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Show the doctor the pack of tablets/granules. Urgent medical treatment may be necessary. You may experience effects such as abdominal pain, diarrhoea, nausea and vomiting, and kidney or liver problems that can be serious.

If you forget to take SIROXTRIN

If you miss a dose, take it as soon as you remember on that day. Take your next dose as scheduled. Do not take a double dose to make up for forgotten individual doses.

If you stop taking SIROXTRIN

Do not stop taking SIROXTRIN unless your doctor tells you to. If you stop taking SIROXTRIN, the excess iron will no longer be removed from your body.

4. Possible side effects

SIROXTRIN can have side effects.

Not all side effects reported for SIROXTRIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SIROXTRIN, please consult your health care provider for advice.

If any of the following happens, stop taking SIROXTRIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.



These are all very serious side effects. If you have them, you may have had a serious reaction to SIROXTRIN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent

- headache,
- diarrhoea (runny tummy), constipation,
- feeling sick (nausea), being sick (vomiting),
- pain in the stomach, bloating, indigestion,
- rash,
- itching,
- a marked decrease in your urine output (sign of kidney problem),
- disturbance in urine test (protein in the urine).

Less frequent

- anxiety,
- sleep disorders,
- dizziness,
- partial loss of vision,
- blurred or cloudy eyesight,
- reduced hearing,
- sore throat,
- inflammation of the lining of the stomach (gastritis),
- vomit blood and/or have black stools,
- abdominal pain, particularly after eating or taking SIROXTRIN,
- heartburn,
- disturbance in kidney function test,



- a combination of drowsiness, upper right abdominal pain, yellowing or increased yellowing of your skin or eyes and dark urine (signs of liver problems),
- gallstones,
- change in the colour of the skin,
- a combination of any of the following symptoms: rash, red skin, blistering of the lips, eyes, or mouth, skin peeling, high fever, flu-like symptoms, enlarged lymph nodes (signs of severe skin reactions),
- glucose in the urine,
- fever,
- swelling,
- tiredness.

Frequency unknown

- a decrease in the number of cells involved in blood clotting (thrombocytopenia), in the number of red blood cells (aggravated anaemia), in the number of white blood cells (neutropenia) or in the number of all kinds of blood cells (pancytopenia),
- a severe rash, or difficulty breathing and dizziness or swelling mainly of the face and throat (signs of severe allergic reaction),
- abnormal level of acid in the blood,
- tear in stomach or intestine wall that can be painful and cause nausea,
- severe upper stomach pain (pancreatitis),
- hives,
- hair loss,
- kidney stones,
- low urine output,
- excessive urination, urinate at night.



You will have some blood tests while taking SIROXTRIN. Your doctor will look for any changes in the kidney function (level of creatinine) or liver function (level of transaminases). Your doctor may also want to test your eyesight and hearing while you are taking SIROXTRIN.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of SIROXTRIN.

5. How to store SIROXTRIN

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Do not use after the expiry date stated on the blister / bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SIROXTRIN contains

- The active substance is deferasirox.
- The other ingredients are anhydrous colloidal silica, crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, purified water



and sodium lauryl sulfate.

What SIROXTRIN looks like and contents of the pack

SIROXTRIN 125: White to off-white coloured flat round uncoated tablets with bevelled edges, debossed with '489' on one side and plain on other side.

SIROXTRIN 250: White to off-white coloured flat round uncoated tablets with bevelled edges, debossed with '490' on one side and plain on other side.

SIROXTRIN 500: White to off-white coloured flat round uncoated tablets with bevelled edges, debossed with '491' on one side and plain on other side.

SIROXTRIN is packed in Alu-Alu blisters (10 tablets per blister) or in HDPE bottles with a child-resistant closure. Pack size: 30 or 100 dispersible tablets. Not all pack sizes may be marketed.

Holder of Certificate of Registration

Trinity Pharma (Pty) Ltd.

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Fourth Floor, Sandton

2031

South Africa

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Registration numbers

SIROXTRIN 125: 561222

SIROXTRIN 250: 561223



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Sequence 0006 – April 2025

SIROXTRIN 500: 561224

Access to the corresponding Professional Information

To be confirmed.

A handwritten signature in dark ink, appearing to be 'BA' followed by a period.