

FERASIRO 90 (DEFERASIROX Film-coated Tablet 90 mg)

FERASIRO 360 (DEFERASIROX Film-coated Tablet 360 mg)

Deferasirox (90 mg and 360 mg Film-Coated Tablets)

What is in this leaflet

1. What FERASIRO is used for
2. How FERASIRO works
3. Before you use FERASIRO
4. How to use FERASIRO
5. While you are using FERASIRO
6. Side effects
7. Storage and Disposal of FERASIRO
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What FERASIRO is used for

FERASIRO 90 mg, and 360 mg Film-Coated Tablets contains an active substance called deferasirox. This medicine is an iron chelator which removes the excess iron from the body (also called iron overload).

☐ Transfusional iron overload (excess amount of iron in patients receiving regular blood transfusions)

FERASIRO is used to treat iron overload caused by repeated blood transfusions. It can be used to treat adults, adolescents, and children aged 2 years and above. Repeated blood transfusions may be necessary in patients suffering from certain types of anemia such as thalassemia, sickle cell disease or myelodysplastic syndromes. However, repeated blood transfusions can cause a build-up of excess iron. This is because blood contains iron and your body does not have a natural way to remove the excess iron you get with your blood transfusions.

☐ Non-transfusion-dependent thalassemia syndromes (excess amount of iron in patients with thalassemia not receiving regular

blood transfusions)

FERASIRO is used to treat patients who have iron overload associated with their thalassemia syndromes, but who are not transfusion dependent. In this case, it can be used to treat adults, adolescents, and children aged 10 years and above.

In patients with non-transfusion-dependent thalassemia syndromes, iron overload may develop over time due to increased absorption of dietary iron in response to low blood cell counts. In thalassemic patients not receiving regular blood transfusions, increased iron levels are usually only observed in patients 10 years of age and above. Over time, the excess iron can damage important organs such as the liver and the heart.

Medicines called iron chelators are used to remove the excess iron and reduce the risk of it causing organ damage.

How FERASIRO works

FERASIRO traps and removes excess iron which is then excreted mainly in the stools.

If you have any questions about how FERASIRO works or why this medicine has been prescribed for you, ask your doctor, pharmacist or healthcare provider.

Before you use FERASIRO

Follow all the doctor's instructions carefully. They may differ from the general information in this leaflet.

When you must not use it

- ☐ If you are allergic (hypersensitive) to deferasirox or any of the other ingredients of FERASIRO listed in this leaflet.
- ☐ If you have severe kidney

problems.

☐ If you have an advanced stage of your myelodysplastic syndrome (MDS) or advanced cancer.

If this applies to you, tell your doctor before taking FERASIRO. If you think you may be allergic, ask your doctor for advice.

Pregnancy and breast-feeding

The effect of FERASIRO on human fertility is not known. FERASIRO is not recommended during pregnancy unless clearly necessary. If you are pregnant or think that you may be, tell your doctor who will discuss with you whether you can take FERASIRO during your pregnancy.

Breastfeeding is not recommended during treatment with FERASIRO. Tell your doctor if you are breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Before you start to use it

Warning and precautions

- ☐ If you have a liver or kidney problem.
- ☐ If you are taking or have recently taken certain painkillers, anti-inflammatory medicines or oral bisphosphonates (see "Taking other medicines").
- ☐ If you are taking or have recently taken anticoagulant medicines (see "Taking other medicines").
- ☐ If you have a low level of platelets or white blood cells in your blood test. If these apply to you, tell your doctor.

Monitoring your FERASIRO treatment

You will have regular tests (blood, urine, or Magnetic Resonance Imaging (MRI)) before and during treatment. These will monitor the amount of iron in your body (level of ferritin) to see

how well FERASIRO is working. The tests are also done to monitor your kidney function (blood level of creatinine, presence of protein in the urine) and liver function (blood level of transaminases, bilirubin and alkaline phosphatase). Your doctor will take these tests into consideration when deciding on the dose of FERASIRO that is the most suitable for you and will also use these tests to decide when you should stop taking FERASIRO.

Your eyesight and hearing will be tested before starting FERASIRO and each year during treatment as a precautionary measure. If you have any questions about how FERASIRO works or why this medicine has been prescribed for you, ask your doctor, pharmacist or healthcare provider.

Older people (65 years of age and above)

FERASIRO can be used by people aged 65 years and over at the same dose as for other adults.

Elderly patients may experience more side effects than younger patients. They should be monitored closely by their doctor for side effects that may require a dose adjustment.

Children and adolescents (age 2 years to 17 years)

FERASIRO can be used in adolescents and children aged 2 years and over. As the patient grows, the doctor will adjust the dose.

Taking other medicines

Antacids (medicines used to treat heartburn) containing aluminum should not be taken at the same time of day as FERASIRO.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes in particular:

- ☐ Midazolam (used to relieve anxiety and/or trouble sleeping)
- ☐ ciclosporin (used in transplantation to prevent graft rejection or for other conditions, e.g. rheumatoid arthritis or atopic dermatitis)

- ☐ simvastatin (used to lower cholesterol)
 - ☐ hormonal contraceptive agents (birth control medicines)
 - ☐ certain painkillers or anti-inflammatory medicines (e.g. aspirin, ibuprofen, corticosteroids)
 - ☐ oral bisphosphonates (used to treat osteoporosis)
 - ☐ anticoagulant medicines (used to prevent or treat blood clotting)
 - ☐ repaglinide (used to treat diabetes)
 - ☐ rifampicin (used to treat tuberculosis)
 - ☐ phenytoin, phenobarbital (used to treat epilepsy)
 - ☐ ritonavir (used in the treatment of HIV infection)
 - ☐ paclitaxel (used in cancer treatment)
 - ☐ theophylline (used to treat respiratory diseases such as asthma)
 - ☐ busulfan (used as treatment prior to bone marrow transplant)
- Your doctor may need to test the level of some of these medicines in your blood. Your doctor will take these tests into consideration when deciding on the most suitable dose of these medicines for you.

How to use FERASIRO

Always take FERASIRO exactly as your doctor has told you.

FERASIRO may be taken either on an empty stomach or with a light meal (less than 50% of calories from fat), preferably at the same time each day.

FERASIRO Film-Coated Tablet is a different formulation of Ferasiro with the same active ingredient, deferasirox; however, the dose will change when switching between Jedoxred Dispersible Tablet and FERASIRO Film-Coated Tablet.

How much to use

- ☐ The dose of FERASIRO is related to body weight for all patients. Your doctor will calculate the dose you need and tell you how many tablets to take each day.
- ☐ The usual daily dose at the start of the treatment is:
 - 14 mg per kilogram body weight for patients receiving regular blood transfusions
 - 7 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 your response to treatment, your doctor may later adjust your treatment to a higher or lower dose.

- ☐ The maximum recommended daily dose is:

- 28 mg per kilogram body weight for patients receiving regular blood transfusions

- 14 mg per kilogram body weight for patients not receiving regular blood transfusions

When and how to take FERASIRO

- ☐ Take FERASIRO once a day, every day, at about the same time each day with some water.

- ☐ Take the tablets either on an empty stomach or with a light meal.

- ☐ If you cannot swallow the tablets whole, you can crush them and sprinkle all of it onto soft food like yoghurt or apple puree. You should then eat it all immediately. Do not keep any to have later.

- ☐ Taking FERASIRO at the same time each day will help you remember when to take your tablets.

How long to use FERASIRO Continue taking FERASIRO every day for as long as your doctor tells you to. This is a long-term treatment, possibly lasting for months or years. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect (see also section: “Monitoring your FERASIRO treatment”).

If you have questions about how long to take FERASIRO, talk to your doctor.

If you forget to use FERASIRO

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 on the next day to make up for the missed dose(s).

If you use too much (overdose) If you have taken too much FERASIRO, or if someone else accidentally takes your tablets, contact your doctor or hospital for advice straight away. Show the doctor the pack of tablets. Urgent medical treatment may be necessary. You may experience

effects such as abdominal pain, diarrhea, nausea and vomiting, and kidney or liver problems that can be serious.

While you are using FERASIRO

Things you must do

- ☐ If you vomit blood and/or have black stools.
 - ☐ If you experience frequent heartburn or abdominal pain (ulcers) particularly after eating or taking FERASIRO.
 - ☐ If you notice a severely decreased urine output (sign of kidney problem).
 - ☐ If you get a severe rash, or difficulty breathing and dizziness or swelling mainly of the face and throat (signs of severe allergic reaction).
 - ☐ If you get 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 and enlarged lymph nodes (signs of severe skin reaction).
 - ☐ If you experience a combination of drowsiness, upper right abdominal pain, yellowing or increased yellowing of your skin or eyes and dark urine (signs of liver problems).
 - ☐ If you experience vision and hearing problems
- If you get any of these symptoms, tell your doctor straight away

Things you must not do

Do not stop taking FERASIRO unless your doctor tells you to. If you stop taking it, the excess iron will no longer be removed from your body (see also above section “How long to take FERASIRO”).

Things to be careful of **Females of child-bearing potential**

FERASIRO may decrease the effect of oral contraceptives or patch contraceptives, therefore you may be at risk of getting pregnant if you are using an oral contraceptive or patch contraceptive only. You should use an additional or different type of contraception.

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

Side effects

Like all medicines, FERASIRO can cause side effects, although not everybody gets them. Most of the side effects are mild to moderate and will generally disappear after a few days to a few weeks of treatment.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Some side effects could be serious but uncommon

- ☐ Vomit blood and/or have black stools.
- ☐ Frequent heartburn, stomach or abdominal pain particularly after eating or taking the drug (signs of ulcer).
- ☐ If you notice a severely decreased urine output (sign of kidney problem).
- ☐ Combination of drowsiness, upper right abdominal pain, yellowing or increased yellowing of your skin or eyes and dark urine (signs of liver problems).
- ☐ Partial loss of vision.
- ☐ Sudden back pain or pain on the right side of the abdomen (signs of gallstones)
- ☐ Severe upper stomach pain (pancreatitis)

Some side effects could become serious but are rare

- Severe skin reactions that might include: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms and enlarged lymph nodes.

If you experience any of these, stop taking the medicine and tell your doctor immediately.

Also reported

- ☐ Tear in stomach or intestine wall that can be painful and cause nausea

Some side effects are very common.

- ☐ Abnormal kidney blood test (increased creatinine)

Some side effects are common .

- ☐ Gastrointestinal disorders, such as nausea, vomiting, diarrhea, pain in the abdomen, bloating, constipation, indigestion
- ☐ Rash
- ☐ Headache
- ☐ Abnormal liver blood tests (increased transaminase)
- ☐ Itching
- ☐ Protein in the urine.

Other side effects are uncommon.

- ☐ Dizziness
- ☐ Fever
- ☐ Blurred or cloudy eyesight
- ☐ Reduced hearing
- ☐ Sore throat
- ☐ Swelling of arms or legs
- ☐ Change in the color of the skin
- ☐ Anxiety
- ☐ Sleep disorder
- ☐ Tiredness

The frequency of some side effects is not known

- ☐ Hair loss
- ☐ A decrease in the number of cells involved in blood clotting (thrombocytopenia), in the number of red blood cells (anaemia aggravated), and in the number of white blood cells (neutropenia)

If any of these affects you severely, tell your doctor.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of FERASIRO

Storage

- ☐ Keep out of the reach and sight of children.
- ☐ Do not use FERASIRO after the expiry date which is stated on the carton after the word ‘EXP’. The expiry date refers to the last day of that month.
- ☐ Do not store above 30°C.
- ☐ Store in the original package in order to protect from moisture.
- ☐ Do not use any pack that is damaged or shows signs of tampering.

Disposal

Medicines should not be disposed of via

wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

□ FERASIRO 90 mg Film-Coated Tablets: Yellow colored, film coated oval, biconvex tablets with beveled edges debossed with 'D' on one side and '90' on another side.

□ FERASIRO 360 mg Film-Coated Tablets: Yellow colored, film coated oval, biconvex tablets with beveled edges debossed with 'D' on one side and '360' on another side.

Ingredients

- Active ingredients

- The active substance is deferasirox.

- Inactive ingredients

- The other ingredients are Microcrystalline Cellulose, Croscarmellose Sodium, Low substituted hydroxypropyl cellulose, Poloxamer 188, Povidone K30, Lactose monohydrate, Colloidal Silicon Dioxide, Sodium Steary Fumarate, Hydrogenated Castor Oil and Opadry Yellow 03H520019

MAL Number:

FERASIRO 90 - MAL23066029AZ
(Deferasirox Film-Coated Tablets 90mg)

FERASIRO 360- MAL23066027AZ
(Deferasirox Film-Coated Tablets 360mg)

Name and Address of Manufacturer

Packed and released by

GoodScience Sdn. Bhd.
No. 7, Jalan KPK 4/3,
Kawasan Perindustrian
Kundang, Kundang Jaya,
48020 Rawang,
Selangor

Manufactured by

Msn Laboratories Private Limited Formulations
Division, Unit-Ii, Sy. No. 1277 & 1319 To
1324, Nandigama (Village & Mandal),
Rangareddy District - 509228, Telangana, India

Product Registration Holder

GoodScience Sdn. Bhd.
No. 7, Jalan KPK 4/3,
Kawasan Perindustrian
Kundang, Kundang Jaya,
48020 Rawang,
Selangor

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