

Irosix Film Coated Tablets

Deferasirox

90 mg, 180 mg and 360 mg Film Coated Tablets

What is in this leaflet

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

What Irosix is used for

Irosix 90 mg, 180 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)

Irosix 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)

Irosix 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 Irosix works

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

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

Before you use Irosix

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 Irosix 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 Irosix. If you think you may be allergic, ask your doctor for advice.

Pregnancy and breast-feeding

The effect of Irosix on human fertility is not known. Irosix 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 Irosix during your pregnancy.

Breastfeeding is not recommended during treatment with Irosix. 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 Irosix 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 Irosix 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 Irosix that is the most suitable for you and will also use these tests to decide when you should stop taking Irosix.

Your eyesight and hearing will be tested before starting Irosix and each year during treatment as a precautionary measure. If you have any questions about how Irosix 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)

Irosix 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)

Irosix 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 Irosix.

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 Irosix

Always take Irosix exactly as your doctor has told you.

Irosix 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.

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

How much to use

- The dose of Irosix 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 Irosix

- Take Irosix 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 Irosix at the same time each day will help you remember when to take your tablets.

How long to use Irosix

Continue taking Irosix 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 Irosix treatment").

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

If you forget to use Irosix

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 Irosix, 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 Irosix

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 Irosix.
- 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 Irosix 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 Irosix").

Things to be careful of
Females of child-bearing potential

Irosix 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 Irosix, do not drive or operate any tools or machines until you are feeling normal again.

Side effects

Like all medicines, Irosix 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 nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Irosix

Storage

- Keep out of the reach and sight of children.
- Do not use Irosix 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.
- Store below 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

- Irosix 90 mg Film Coated Tablets: Light blue color, oval, biconvex film coated tablet with bevelled edges, debossed with "N55" on one side and plain on other side.
- Irosix 180 mg Film Coated Tablets: Medium blue color, oval, biconvex film coated tablet with bevelled edges, debossed with "N54" on one side and plain on other side.

Irosix 360 mg Film Coated Tablets: Dark blue color, oval, biconvex film coated tablet with bevelled edges, debossed with "N53" on one side and plain on other side.

- *Active ingredients*

- The active substance is deferasirox.

- *Inactive ingredients*

- The other ingredients are Microcrystalline Cellulose; Crospovidone; Povidone ; Magnesium Stearate;; Poloxamer; Opadry Complete Film Coating System 00F505009 Blue, Opadry Complete Film Coating System 00F505008 Blue, Opadry Complete Film Coating System 00F505007 Blue.

MAL Number

Irosix 90 mg Film Coated Tablet:
MAL22066014AZ

Irosix 180 mg Film Coated Tablet:
MAL22066015AZ

Irosix 360 mg Film Coated Tablet
MAL22066013AZ

Irosix are available in Clear PVC/PVDC/Alu blister (90mg, 180mg & 360mg) and 40cc HDPE bottle (180mg).

Manufacturer

Novugen Pharma Sdn. Bhd.
No.27, Jalan Lengkuk Teknologi 2,
Taman Teknologi Enstek Fasa 1,
71760 Bandar Baru Enstek,
Negeri Sembilan, Malaysia.

Product Registration Holder

Novugen Pharma Sdn. Bhd.
No.3, Jalan Jururancang U1/21,
Hicom Glenmarie Industrial Park,
40150, Shah Alam,
Selangor, Malaysia.

Date of revision

19/08/2022

Serial Number

NPRA (R2) 22/018