

GENSIROX FILM-COATED TABLETS

Deferasirox (90mg, 180mg, 360mg)

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What GENSIROX is used for

GENSIROX 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)

GENSIROX 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)

GENSIROX 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 GENSIROX works

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

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

Before you use GENSIROX

GENSIROX 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 GENSIROX Film-Coated Tablet.

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 GENSIROX 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 GENSIROX.

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

Pregnancy and lactation

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

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

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

- Before you start 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 GENSIROX 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 GENSIROX 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 GENSIROX that is the most suitable for you and will also use these tests to decide when you should stop taking GENSIROX.

Your eyesight and hearing will be tested before starting GENSIROX and each year during treatment as a precautionary measure.

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

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Older people (65 years of age and above)

GENSIROX 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)

GENSIROX 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 GENSIROX.

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 GENSIROX

Always take GENSIROX exactly as your doctor has told you.

GENSIROX 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.

- How much to use

The dose of GENSIROX 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 to use it

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

- How long to use it

Continue taking GENSIROX 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 GENSIROX treatment").

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

- If you forget to use it

If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then. Do not take a double dose to make up for a forgotten tablet.

- If you use too much (overdose)

If you have taken too much GENSIROX, 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 it

- Things you must do

If you get any of these symptoms, tell your doctor straight away

- If you vomit blood and/or have black stools.
- If you experience frequent heartburn or abdominal pain (ulcers) particularly after eating or taking GENSIROX.
- If you notice a severely decreased urine output (sign of kidney problem).
- If you get a severe rash, or difficulty breathing and dizziness

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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

- Things you must not do

Do not stop taking GENSIROX 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 GENSIROX")

- Things to be careful of

Females of child-bearing potential

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

Side effects

Like all medicines, GENSIROX 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

(These side effects may affect up to 1 in every 10,000 people).

- 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 (frequency unknown)

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

Some side effects are very common (These side effects may affect more than 1 in every 10 people).

- Abnormal kidney blood test (increased creatinine)

Some side effects are common (These side effects may affect up to 1 in every 10 people).

- 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 (These side effects may affect up to 1 in every 100 people).

- 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 npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of GENSIROX

- Storage

- Store below 30°C. Store in the original package in order to protect from moisture.
- Keep out of the reach and sight of children.
- Do not use GENSIROX 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 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

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measures will help to protect the environment.

Product Description

- What it looks like

GENSIROX 90 MG FILM-COATED TABLETS:

Light Blue to Light Whitish Blue, oval, biconvex, film-coated tablet with beveled edges, debossed with “L” on one side and “663” on the other side.

GENSIROX 180 MG FILM-COATED TABLETS:

Medium Blue to Light Whitish Blue, oval, biconvex, film-coated tablet with beveled edges, debossed with “L” on one side and “664” on the other side.

GENSIROX 360 MG FILM-COATED TABLETS:

Dark Blue to Blue, oval, biconvex, film-coated tablet with beveled edges, debossed with “L” on one side and “665” on the other side.

- Ingredients

Active ingredient:

Deferasirox.

Inactive ingredients:

- Cellulose, Microcrystalline (Avicel PH 102)
- Crospovidone (Polyplasdone XL)
- Silica, Colloidal anhydrous (Aerosil 200 Pharma)
- Povidone (K-30)
- Poloxamer 188 (Lutrol F 68)
- Isopropyl Alcohol (3)
- Water
- Purified (3)
- Sodium Starch Glycolate Type-A
- Magnesium Stearate (Vegetable Source)
- Opadry 00F505018 Blue (used in strength 90mg)
- Opadry 00F505011 Blue (used in strength 180mg)
- Opadry 00F505017 Blue (used in strength 360mg)

- MAL number(s):

GENSIROX 90 MG FILM-COATED TABLETS:

MAL26036037AZ

GENSIROX 180 MG FILM-COATED TABLETS:

MAL26036038AZ

GENSIROX 360 MG FILM-COATED TABLETS:

MAL26036039AZ

Manufacturer

Alembic Pharmaceuticals Limited
(Formulation- 1 Unit),
Village Panelav, Post Tajpura Near Baska,
Taluka Halol, Panchmahal, 389350 Gujarat, India.

Product Registration Holder

GENPHARMA SDN. BHD.
Lot 5016, Jalan Teratai,
5 ½ Mile Off Jalan Meru,
41050 Klang, Selangor, Malaysia

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29/7/2026

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